Date/Time:05-SEP-2014;16:24:57

AER Selection Criteria

General Information
AER deleted is Equal to : 0
AER last approved is Equal to : 1
AER number is Equal to : PSUR%

Standard SQL Query
(SELECT (A.AER_ID) FROM AER A WHERE 1 = 1 AND A.AER_DELETED = 0 AND (UPPER(A.AER_NO) >= UPPER('PSUR_111') AND UPPER(A.AER_NO) <= UPPER('PSUR_112')))

Count of AERs
No. of AERs that satisfy the Query :0
No. of AERs selected for the Report :112

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

SELECTION CRITERIA

General Layout

From	: 01-JAN-2014
To	: 01-JAN-2014
Date type:	: Received date
Alert Date From	: Received date
Non Alert Date From	: Received date
Authority	:
Labeling Country	: USA
Reporting Language	: English :(Implied)
Initial and Follow-up cases	: Together
Print option	: Initial and Follow-up cases
WHO DD	:
Trade Name	: Crocin
Tradename Type	: Product Description
Internal Drug Code	:
Approval Number	:
Approval Country	:
Approval Type	:
Route of Admin	:
Form of Admin	:
Protocol no.	:
Project no.	:
Medically	: Both
Listedness from	: AER
Consider Null Values	: No
Ignore Not Relevant	: No
Include solicited cases	: No
Case reports	: FDA3500a
Country for CIOMS	:
Report type	: Blinded
Prevent blinded cases in unblinded report	: No
If no access to unblinded data	: Print blinded info.
Missing Date	: Miss Date

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

SELECTION CRITERIA

Missing Text	: Miss Txt
Imprecise Date	: Imp
Date Separator	: -
Print ICHLL Sub-Report	: Yes
Print Summary Tabulation Sub-Report	: Yes
Print Selection Criteria Sub-Report	: Yes
Print Exception List	: Yes
Print report generation date and time	: No
Date Format	: DDMONYYYY
AER file name	: E:\AG633.26\B1A4\Repsrv\webreports\out\R1555_112121121.txt

ICHLL

Reported AER No.	: Local AER no.
Follow-up No. with AER No.	: Yes
Sources	: Primary sources
Print child data	: Yes
Include dose no	: Yes
AE Onset Date, or the Latency for the reaction	: AE Onset date
Print indexes without data	: Yes
Print ICHLL page No.	: Yes
Starting ICHLL page No.	: 1 (Implied)
Drug name type	: Trade Name
Formulation in Drug name	: Yes
Co-manifestation reactions	: No
Include dose with Unit dose	: Yes
Include dose with Frequency	: Yes
Include dose with Strength	: Yes
Include dose with Formulation	: Yes
Include dose with Route	: Yes
Group by Indication	: Separate
Group by SOC	: Separate
Group all reactions, regardless of source	: Separate
Group all serious/non-serious reactions	: Separate

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

SELECTION CRITERIA

Group all listed/unlisted reactions	: Separate
Suspect Drug with	: Ingr
Concomitant Drug with	: Full WHO DD Decode
ICHLL page Title 1	:
ICHLL page Title 2	:
ICHLL page Title 3	:
ICHLL page Footer 1	:
ICHLL page Footer 2	:
ICHLL Report Footer 1	:
ICHLL Report Footer 2	:
ICHLL Report Footer 3	:
ICHLL Report Footer 4	:
ICHLL Report Footer 5	:
ICHLL Report Footer 6	:
Include Serious info.	: Yes
Include Labeling info	: Yes
Include Casuality info.	: Yes
Include De/Rechallenge	: Yes
Include Disease data	: Yes
Include Indication for use	: Yes
Include Study info	: Yes
Include Authority-id	: Yes
Include Literature data	: Yes
Include Suspect drugs	: Yes
Include Interacting drugs	: Yes
Include Co-Meds	: Yes
Include Pharmacovig comments	: Yes
Include Company remarks	: Yes
Summary option	: Do not print
Include Serious, Labeled, Spontaneous cases	: Yes
Include Serious, Unlabeled, Spontaneous cases	: Yes
Include Non-Serious, Labeled, Spontaneous cases	: Yes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

SELECTION CRITERIA

Include Non-Serious, Unlabeled, Spontaneous cases	: Yes
Include Serious, Labeled, Study cases	: Yes
Include Serious, Unlabeled, study cases	: Yes
Include Non-Serious, Labeled, Study cases	: Yes
Include Non-Serious, Unlabeled, study cases	: Yes
Include Serious, Labeled, Literature cases	: Yes
Include Serious, Unlabeled, Literature cases	: Yes
Include Non-Serious, Labeled, Literature cases	: Yes
Include Non-Serious, Unlabeled, Literature cases	: Yes
Include Serious, Labeled, Authority cases	: Yes
Include Serious, Unlabeled, Authority cases	: Yes
Include Non-Serious, Labeled, Authority cases	: Yes
Include Non-Serious, Unlabeled, Authority cases	: Yes
Include Serious, Labeled, other cases	: Yes
Include Serious, Unlabeled, other cases	: Yes
Include Non-Serious, Labeled, other cases	: Yes
Include Non-Serious, Unlabeled, other cases	: Yes

Summary Tabulation

Print a page of a SumTab even if no data is available	: Yes
Print SumTab page no.	: Yes
Starting SumTab page no.	: 1 (Implied)
Group all reactions, regardless of source	: Separate
Group all serious/non-serious reactions	: Separate
Group on Indication	: Yes
Sort order for reactions under SOC	: By Alphanumeric
SumTab page Title 1	:
SumTab page Title 2	:
SumTab page Title 3	:
SumTab page Footer 1	:
SumTab page Footer 2	:
SumTab Report Footer 1	:
SumTab Report Footer 2	:

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

SELECTION CRITERIA

SumTab Report Footer 3	:
SumTab Report Footer 4	:
SumTab Report Footer 5	:
SumTab Report Footer 6	:
Include Serious, Labeled, Spontaneous cases	: Yes
Include Serious, Unlabeled, Spontaneous cases	: Yes
Include Non-Serious, Labeled, Spontaneous cases	: Yes
Include Non-Serious, Unlabeled, Spontaneous cases	: Yes
Include Serious, Labeled, Study cases	: Yes
Include Serious, Unlabeled, Study cases	: Yes
Include Non-Serious, Labeled, Study cases	: Yes
Include Non-Serious, Unlabeled, Study cases	: Yes
Include Serious, Labeled, Literature cases	: Yes
Include Serious, Unlabeled, Literature cases	: Yes
Include Non-Serious, Labeled, Literature cases	: Yes
Include Non-Serious, Unlabeled, Literature cases	: Yes
Include Serious, Labeled, Authority cases	: Yes
Include Serious, Unlabeled, Authority cases	: Yes
Include Non-Serious, Labeled, Authority cases	: Yes
Include Non-Serious, Unlabeled, Authority cases	: Yes
Include Serious, Labeled, other cases	: Yes
Include Serious, Unlabeled, other cases	: Yes
Include Non-Serious, Labeled, other cases	: Yes
Include Non-Serious, Unlabeled, other cases	: Yes

Dictionary

Dictionary Type	: MEDDRA
ART Term type	: Reported term , Preferred term , Included term , Code from ART Dictionary
Disease Dictionary type	: MedDRA

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Spontaneous/Authority, Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Spontaneous/Authority, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Spontaneous/Authority, Non-Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Spontaneous/Authority, Non-Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_111	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1110	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11100	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11101	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11102	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11103	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11104	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11105	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11106	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11107	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11108	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11109	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1111	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11110	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11111	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11112	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11113	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11114	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11115	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11116	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11117	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11118	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11119	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1112	USA	Clinical S	23A-	M	Mi-	, , , ,	01-Jan-2014 -	Miss Txt	FEVER (Miss Txt,	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
			dult		ss Txt	,	02-Feb-2014		Miss Txt)		
PSUR_11120	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11121	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11122	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11123	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11124	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11125	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11126	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11127	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11128	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11129	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1113	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11130	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11131	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11132	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11133	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11134	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11135	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11136	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11137	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11138	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11139	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1114	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11140	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11141	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11142	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11143	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11144	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11145	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11146	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11147	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11148	USA	Clinical S	23A-	M	Mi-	, , , ,	01-Jan-2014 -	Miss Txt	FEVER (Miss Txt,	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
			dult		ss Txt	,	02-Feb-2014		Miss Txt)		
PSUR_11149	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1115	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11150	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11151	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11152	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11153	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11154	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11155	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11156	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11157	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11158	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11159	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1116	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11160	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11161	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11162	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11163	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11164	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11165	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11166	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11167	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11168	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11169	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_1117	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11170	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11171	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11172	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11173	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11174	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11175	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11176	USA	Clinical S	23A-	M	Mi-	, , , ,	01-Jan-2014 -	Miss Txt	FEVER (Miss Txt,	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
			dult		ss Txt	,	02-Feb-2014		Miss Txt)		
PSUR_11177	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11178	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11179	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1118	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11180	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11181	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11182	USA	Clinical S	23A-dult	M	Mi-ss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11183	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11184	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11185	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11186	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11187	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11188	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11189	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_1119	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11190	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11191	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11192	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11193	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11194	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11195	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11196	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11197	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments
PSUR_11198	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_11199	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled
PSUR_112	USA	Clinical S	23A-dult	M	Miss Txt	, , , , ,	01-Jan-2014 - 02-Feb-2014	Miss Txt	FEVER (Miss Txt, Miss Txt)	Miss Txt	Serious, Labeled

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Non-Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Study, Non-Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Literature, Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Literature, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Literature, Non-Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Literature, Non-Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Others, Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Others, Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Others, Non-Serious, Unlabeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Indication:
SOC:
Others, Non-Serious, Labeled

Case Ref. No.	Country	Source	Age	Sex	Dose No.	D.Dose	Therapy Dates /Duration	Onset Date /Latency	Reaction	Outcome	Comments

No data selected

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Spontaneous/Authority Reports
All Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Spontaneous/Authority Reports
All Non-Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Clinical Trials Reports
All Serious Reactions

Indication Term SOC ADR Term		U	L	Total # of AEs
FEVER (Miss Txt, Miss Txt)		0	112	112
	Sub Total # of AEs	0	112	112
	Sub Total # of Cases	0	112	112
Total # of AEs		0	112	112
Total # of Cases		0	112	112

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Clinical Trials Reports
All Non-Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Literature Reports
All Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Literature Reports
All Non-Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Other Sources Reports
All Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin **Date Range : 01-JAN-2014 - 01-JAN-2014**

Other Sources Reports
All Non-Serious Reactions

Indication Term SOC ADR Term	U	L	Total # of AEs
Total # of AEs	0	0	0
Total # of Cases	0	0	0

'-': Place holder for turned off indexes

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

Date Range : 01-JAN-2014 - 01-JAN-2014

Spontaneous/Authority, Study, Literature and Other Reports
Count of Cases

	Spontaneous/ Authority	Study	Literature	Others
Total # of AEs				
Total # of Cases	0	112	0	0
	0	112	0	0

'-': Place holder for turned off indexes

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_111(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_111(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_1110(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_1110(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11100(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11100(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11101(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11101(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11102(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11102(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11103(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11103(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11104(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11104(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11105(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11105(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11106(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11106(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11107(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11107(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

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FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11108(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11108(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11109(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11109(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 **of** 1

Mfr Report # PSUR_1111(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_1111(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11110(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11110(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11111(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11111(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11112(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11112(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11113(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11113(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11114(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11114(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11115(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11115(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11116(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11116(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11117(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11117(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 **of** 1

Mfr Report # PSUR_11118(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**
PSUR_11118(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11119(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1 Crocin(ING-0001)

#2

2. **Dose, Frequency & Route Used**

#1

#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*

#1 01/01/2014 - 02/02/2014

#2

4. **Diagnosis for Use** *(Indication)*

#1

#2

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**

#1

#2

7. **Exp. Date**

#1

#2

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11119(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_1112(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_1112(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11120(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11120(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11121(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11121(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11122(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11122(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

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Mfr Report # PSUR_11123(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11123(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11124(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**
PSUR_11124(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11125(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11125(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

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Mfr Report # PSUR_11126(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11126(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

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Mfr Report # PSUR_11127(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11127(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

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FORM FDA 3500A (1/09)

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Mfr Report # PSUR_11128(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11128(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11129(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11129(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_1113(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_1113(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11130(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11130(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

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Mfr Report # PSUR_11131(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

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3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

☐ 5-day	☐ 30-day
☐ 7-day	☐ Periodic
☐ 10-day	☒ Initial
☐ 15-day	☐ Follow-up # _____

9. **Manufacturer Report Number**
PSUR_11131(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

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Mfr Report # PSUR_11132(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

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   - ☐ Disability or Permanent Damage
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   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
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C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

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10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
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   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11132(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

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FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
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   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

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C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11133(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

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Mfr Report # PSUR_11134(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
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3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11134(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

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Mfr Report # PSUR_11135(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11135(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11136(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11136(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11137(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11137(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11138(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11138(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11139(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11139(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_1114(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_1114(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11140(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11140(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11141(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*

#1 Crocin(ING-0001)

#2

2. **Dose, Frequency & Route Used**

#1

#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*

#1 01/01/2014 - 02/02/2014

#2

4. **Diagnosis for Use** *(Indication)*

#1

#2

5. **Event Abated After Use Stopped or Dose Reduced?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**

#1

#2

7. **Exp. Date**

#1

#2

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11141(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11142(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11142(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11143(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11143(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11144(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

☐ 5-day	☐ 30-day	☒ Initial	
☐ 7-day	☐ Periodic		
☐ 10-day	☒ Initial		
☐ 15-day	☐ Follow-up # _____		

9. **Manufacturer Report Number**
PSUR_11144(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11145(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT (In confidence)
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11145(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11146(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

8. **Adverse Event Term(s)**

9. **Manufacturer Report Number**: PSUR_11146(0)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11147(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time	3. Sex	4. Weight
PAT In confidence	of Event: 23 Adult or Date of Birth:	☐ Female ☒ Male	_____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability or Permanent Damage
- ☐ Congenital Anomaly/Birth Defect
- ☐ Other serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. **Date of Event** *(mm/dd/yyyy)*

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1 Crocin(ING-0001)
#2

2. **Dose, Frequency & Route Used**
#1
#2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 01/01/2014 - 02/02/2014
#2

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1
#2

7. **Exp. Date**
#1
#2

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***

002
(Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*

- ☐ Foreign
- ☒ Study
- ☐ Literature
- ☐ Consumer
- ☐ Health Professional
- ☐ User Facility
- ☐ Company Representative
- ☐ Distributor
- ☐ Other: _____

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5.
(A)NDA # _____
IND # _____
STN # _____
PMA/510(k) # _____
Combination Product ☐ Yes
Pre-1938 ☐ Yes
OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*

- ☐ 5-day ☐ 30-day
- ☐ 7-day ☐ Periodic
- ☐ 10-day ☒ Initial
- ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**
PSUR_11147(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.

FDA Facsimile Approval: 05/09/2006 (ArisGlobal, LLC)

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500A (1/09)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Mfr Report # PSUR_11148(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. **Patient Identifier**: PAT — In confidence
2. **Age at Time of Event:** 23 Adult or **Date of Birth:**
3. **Sex**: ☐ Female ☒ Male
4. **Weight**: _____ lbs or _____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other serious (Important Medical Events)

3. **Date of Event** *(mm/dd/yyyy)*:

4. **Date of This Report** *(mm/dd/yyyy)*: 09/05/2014

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*
   No Risk Factor Available

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

3500A Facsimile

C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
   #1 Crocin(ING-0001)
   #2

2. **Dose, Frequency & Route Used**
   #1
   #2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
   #1 01/01/2014 - 02/02/2014
   #2

4. **Diagnosis for Use** *(Indication)*
   #1
   #2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
   #1
   #2

7. **Exp. Date**
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*
    Concomitant Drug Not Available

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   002
   (Initial Unit)

2. **Phone Number**

3. **Report Source** *(Check all that apply)*
   - ☐ Foreign
   - ☒ Study
   - ☐ Literature
   - ☐ Consumer
   - ☐ Health Professional
   - ☐ User Facility
   - ☐ Company Representative
   - ☐ Distributor
   - ☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*: 01/01/2014

5. (A)NDA # _____
   IND # _____
   STN # _____
   PMA/510(k) # _____
   Combination Product ☐ Yes
   Pre-1938 ☐ Yes
   OTC Product ☐ Yes

6. **If IND, Give Protocol #**

7. **Type of Report** *(Check all that apply)*
   - ☐ 5-day ☐ 30-day
   - ☐ 7-day ☐ Periodic
   - ☐ 10-day ☒ Initial
   - ☐ 15-day ☐ Follow-up # _____

9. **Manufacturer Report Number**: PSUR_11148(0)

8. **Adverse Event Term(s)**

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. **Health Professional?** ☐ Yes ☐ No

3. **Occupation**

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☐ No ☐ Unk.