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_11149(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_11149(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.

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

MEDWATCH

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Mfr Report # PSUR_1115(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_1115(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.

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

MEDWATCH

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Mfr Report # PSUR_11150(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_11150(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.

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

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Mfr Report # PSUR_11151(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_11151(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.

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

MEDWATCH

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Mfr Report # PSUR_11152(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11152(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.

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

MEDWATCH

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Mfr Report # PSUR_11153(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_11153(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.

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_11154(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_11154(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_11155(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_11155(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.

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_11156(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11156(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.

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

MEDWATCH

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

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Mfr Report # PSUR_11157(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11157(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.

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

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Mfr Report # PSUR_11158(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_11158(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.

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_11159(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_11159(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.

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_1116(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_1116(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.

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_11160(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_11160(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.

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_11161(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_11161(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.

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_11162(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_11162(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.

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_11163(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

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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_11163(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.

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_11164(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_11164(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.

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_11165(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_11165(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.

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_11166(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_11166(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_11167(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_11167(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.

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_11168(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_11168(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.

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_11169(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_11169(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.

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_1117(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_1117(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.

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_11170(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_11170(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.

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_11171(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_11171(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.

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_11172(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_11172(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.

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

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Mfr Report # PSUR_11173(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_11173(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.

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

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Mfr Report # PSUR_11174(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_11174(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.

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

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Mfr Report # PSUR_11175(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_11175(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.

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

MEDWATCH

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

Mfr Report # PSUR_11176(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_11176(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.

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

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Mfr Report # PSUR_11177(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11177(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.

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

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Mfr Report # PSUR_11178(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11178(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.

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

MEDWATCH

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

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Mfr Report # PSUR_11179(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_11179(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.

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

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Mfr Report # PSUR_1118(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_1118(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.

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

MEDWATCH

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Mfr Report # PSUR_11180(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_11180(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.

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

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Mfr Report # PSUR_11181(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_11181(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.

U.S. Department of Health and Human Services
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Mfr Report # PSUR_11182(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	23 Adult or	☐ 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	3. Therapy Dates *(If unknown, give duration)* from/to (or best estimate)
#1	#1 01/01/2014 - 02/02/2014
#2	#2

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#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_11182(0)

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

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

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

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Mfr Report # PSUR_11183(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
- ☐ 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_11183(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.

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

MEDWATCH

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Mfr Report # PSUR_11184(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_11184(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.

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

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Mfr Report # PSUR_11185(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_11185(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

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Mfr Report # PSUR_11186(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_11186(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.

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

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Mfr Report # PSUR_11187(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_11187(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

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Mfr Report # PSUR_11188(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

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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_11188(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.

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

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Mfr Report # PSUR_11189(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_11189(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

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Mfr Report # PSUR_1119(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_1119(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.

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_11190(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_11190(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

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Mfr Report # PSUR_11191(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_11191(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

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

Mfr Report # PSUR_11192(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_11192(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.

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

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Mfr Report # PSUR_11193(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	23 Adult or	☐ 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.

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

4. Diagnosis for Use *(Indication)*	5. Event Abated After Use Stopped or Dose Reduced?
#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?
#1	#1	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2	#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_11193(0)

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

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

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

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Mfr Report # PSUR_11194(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_11194(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.

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

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Mfr Report # PSUR_11195(0)

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: / Date of Birth:	3. Sex	4. Weight
PAT In confidence	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_11195(0)

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

E. INITIAL REPORTER

1. **Name and Address**

Phone #

2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA
☐ Yes ☐ No		☐ Yes ☐ No ☐ Unk.

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

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Mfr Report # PSUR_11196(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_11196(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.

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_11197(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_11197(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.

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_11198(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_11198(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)

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Page 1 **of** 1

Mfr Report # PSUR_11199(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_11199(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.

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

MEDWATCH

FORM FDA 3500A (1/09)

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Page 1 **of** 1

Mfr Report # PSUR_112(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_112(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.

PERIODIC SAFETY UPDATE REPORT

Drug : Crocin

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

EXCEPTION LIST

AER No	Version No	Local Version No	Exception

No data selected