Wholesaler Product Return Letter

Isotretinoin Return Customer Instruction Guide - Wholesaler

Wholesaler Name  
Address 1  
Address 2  
City, State Postal Code

Dear Wholesaler:

You are no longer registered in the iPLEDGE Program for the following reason:

- Your facility is closing, and will no longer be a wholesaler in the iPLEDGE Program.

Therefore, you are required to return all isotretinoin inventories in stock effective immediately.

This action is pursuant to the FDA approval of the iPLEDGE Program through the special restricted distribution program. If you have questions about your status in the iPLEDGE Program, please call 1-866-495-0654 or visit www.ipledgeprogram.com for more information.

**Action required by a wholesaler no longer registered in the iPLEDGE Program:**

- Immediately remove all isotretinoin from your stock.
- If you have isotretinoin inventory, please call **1-866-495-0654** for further instructions on returning this product to the manufacturer.

Sincerely,

iPLEDGE Program Sponsors

www.ipledgeprogram.com  |  1-866-495-0654
SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE®. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

iPLEDGE, an enhanced pregnancy risk management program designed to minimize fetal exposure to isotretinoin, has been approved by the FDA through a special restricted distribution program.

www.ipledgeprogram.com     1-866-495-0654
[Name of Manufacturer]

(Product Name and Generic Designation) Wholesaler to Wholesaler Shipment Request Form

REQUESTING PARTY INFORMATION: (Please print or type)
Requester Name: ____________________________________________________ Telephone: _______________
E-Mail Address: _____________________________ Date of Request: ________________
Wholesaler Name: _______________________________________________ DEA: _______________________
Address: ____________________________ City:________________ St ate:_________ Zip:__________
Requesting Party represents and warrants that the Receiving Party listed below is registered with the iPLEDGE Program.
Requester Signature: ________________________________________ Date: ____________________________

RECEIVING PARTY INFORMATION

Wholesaler Name: ______________________________________________ DEA: ________________________
Address: ____________________________ City:______________ St ate:_________ Zip:___________
Ship to Address: ____________________________ City: _________________ St ate: ______ Zip: ________

MANUFACTURER’S CONSENT

Shipments of [Product Name and Generic Designation] between wholesalers* must be in compliance with the iPLEDGE Program. Labeling for [Product Name] states that wholesalers registered in the iPLEDGE Program may only ship to other registered wholesalers with prior written consent from the manufacturer. Pursuant to the labeling for [Product Name], the authorized signature below shall serve as written consent from the manufacturer provided that the requesting and receiving party’s registration is verified prior to each shipment. Registration will be verified by [Manufacturer Name] upon receipt of shipment request.

*The term wholesaler refers to a wholesaler and each of its individual distribution centers, a distributor and each of its individual distribution centers, and/or each warehousing chain pharmacy distribution center.

NOTE: This Wholesaler to Wholesaler Shipment Request Form is not required when shipping isotretinoin between distribution centers that are under the same parent company.

[Name of Manufacturer]

By: _____________________________________________________ Title: ______________________________ ___
Print Name: ______________________________________________ Date: _________________________________

Please return completed forms to [Insert Appropriate Information Including Fax Number, Email URL, Telephone Number, etc.]

Please note that this approval is for a one time shipment. Further shipments require consent from [Manufacturer].
FDA REMS Submission

Patient Screens Inventory

iPLEDGE Program

Revised: December 2017
Patient Screens Inventory:

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Patient Registration from Public Home Page

Patient Registration

Patients cannot register directly in the iPLEDGE Program. All Patients are registered in iPLEDGE by a Prescriber. A Prescriber is a medical professional such as a doctor. If you believe you should be registered in the iPLEDGE Program, please contact your Prescriber.
Patient Home Page for Patient in Program Status “Required to Demonstrate Comprehension”

SAFETY NOTICE

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Answer the Comprehension Questions Section:

The iPLEDGE Program requires you to answer comprehension questions before every prescription. These questions will demonstrate your understanding of the iPLEDGE Program requirements. If you have not answered the questions, you may not obtain your prescription until you have correctly answered the questions. You may use your iPLEDGE educational kit as a resource as you answer the questions.

How to Report?

Call our toll free number 1-866-495-0654 to report any of the following:

- An Adverse Event: If you or someone you know has experienced an adverse event, please call 1-866-495-3054.
- A Pregnancy: To report a pregnancy, please call 1-866-495-0654.
Patient Home Page for Patient Not in Program Status “Required to Demonstrate Comprehension”
Patient – Comprehension Questions - Did not fill Rx in previous window

Answer Your Questions

Before You Get Started

iPLEDGE Program has no record of you filling a prescription in your prescription window from [month day, year] through [month day, year]. Did you fill your prescription during this prescription window?

- Yes
- No

Note: Your answer will not restrict you from getting your prescription.

Submit

Reminder: Please be sure that your prescriptions are authorized in the iPLEDGE Program system by the Pharmacy. If the Pharmacy does not authorize the prescription in the iPLEDGE Program system, it could result in an unnecessary interruption in your treatment. Ask the Pharmacy if they have authorized this prescription and look for the iPLEDGE Program sticker on your prescription bag. You may find a participating Pharmacy by using the Find a Pharmacy feature on the iPLEDGE Program website.
Answer Your Questions

Please follow these two steps to demonstrate iPLEDGE Program comprehension.

Step 1: Birth Control Verification

Please enter the two methods of birth control that you are using. These must be the same two methods that you have told your Doctor that you are using. The answers you provide are used to determine what questions should be asked in step 2 below.

Additionally, the first month that you answer your questions, you will be asked a series of questions about information and counseling provided to you. There are no wrong answers to these questions. The answers are used to determine how often the iPLEDGE Program materials are shared with patients.

Step 2: Comprehension Questions

In order to get a prescription of isotretinoin, you must demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. You will be shown a series of questions and a list of multiple choice answers for each question. Only one of the answers will be the right answer for each question. If you choose the right answer, you will move on to the next question. If you choose the wrong answer, you will be shown the right answer for that question, and then you will move on to the next question.

When you have answered all the questions, you will be notified right away if you have passed or not. If you did not pass, you will be shown a list of the questions you got wrong and the right answers for those questions. You will also be shown where to find more information on these questions. You may attempt to answer the questions again after reviewing this information.

You will be allowed to obtain your prescription once you have correctly answered these questions.

Continue
If the patient selects abstinence, they will not be allowed to select a second method of birth control.
Patient – Comprehension Questions - Patient Contraception and First Month Questions

Birth Control Verification

All fields listed below are required unless otherwise indicated.
Please select your birth control methods by clicking the Submit button.

Primary
Birth Control Pills

Secondary
Male Latex Condom

Did your doctor or anyone in your doctor’s office tell you that it is important not to become pregnant while taking isotretinoin?

Yes
No

Did you receive the Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant?

Yes
No

If yes, did you read

1. The Guide to Isotretinoin for Female Patients Who Can Get Pregnant?
   - Yes
   - No

2. The Birth Control Workbook?
   - Yes
   - No

Did you watch the video, “Be Prepared, Be Protected” about birth control?

- Yes
- No

Did you watch the video, “Be Aware: The Risk of Pregnancy While on Isotretinoin” about the effects of isotretinoin?

- Yes
- No

Did your doctor or anyone in your doctor’s office offer to refer you to another health care provider for birth control counseling?

- Yes
- No

From whom did you receive birth control counseling?

- My doctor
- Another health care provider
- I did not receive birth control counseling

Submit
Birth Control Verification

All fields listed below are required unless otherwise indicated.

Please select your birth control methods click the Submit button.

Primary

- Birth Control Pills
- Hormonal Implant
- Hormonal IUD
- Non-hormonal IUD
- Tubal Sterilization
- Male Vasectomy
- Natural Family Planning
- Hormonal Shot
- Hormonal Vaginal Ring
- Hormonal Skin Patch
- Birth Control Pills (Combination Type)
- Progestrone-only Mini-pills
- Abstinence

Did you watch the video, “Be Prepared, Be Protected” about birth control?
- Yes
- No

Did you watch the video, “Be Aware: The Risk of Pregnancy While on Isotretinoin” about the effects of isotretinoin?
- Yes
- No

Did your doctor or anyone in your doctor's office offer to refer you to another health care provider for birth control counseling?
- Yes
- No

From whom did you receive birth control counseling?
- My doctor
- Another health care provider
- I did not receive birth control counseling

Submit
Patient – Comprehension Questions – Barrier/Primary (First Time):

Birth Control Verification

All fields listed below are required unless otherwise indicated.
Please select your birth control methods click the Submit button.

Primary
- Birth Control Pills

Secondary
- Hormonal IUD
- Hormonal Implant

You should not become pregnant while taking

Educational Kit For Female Patients Who Can Get Pregnant?

Counseling about birth control?

- Yes
- No

Did your doctor or anyone in your doctor’s office offer to refer you to another health care provider for birth control counseling?

- Yes
- No

From whom did you receive birth control counseling?

- My doctor
- Another health care provider
- I did not receive birth control counseling

Submit
Patient – Comprehension Questions – Barrier/Primary (Subsequent):

Birth Control Verification

All fields listed below are required unless otherwise indicated.
Please select your birth control methods by clicking the Submit button.

Primary
- Birth Control Pills

Secondary
- Hormonal IUD
- Hormonal Implant
- Hormonal IUD
- Non-hormonal IUD
- Tubal Ligation
- Male Vasectomy
- Natural Family Planning
- Hormonal Shot
- Hormonal Vaginal Ring
- Female Condom
- Hormonal Skin Patch
- Birth Control Pills (Combination Type)
- Progestosterone-only Mini-pills
- Male Latex Condom
- Cervical Cap with a Spermicide
- Diaphragm with a Spermicide
- Vaginal Sponge
- Cervical Shield
- Withdrawal

Submit
Comprehension Questions – Sample Question

You are in your third month of treatment, in order to get your isotretinoin prescription, you must:

- Have a urine test for infection.
- Have a negative pregnancy test done in a laboratory, discuss birth control with your doctor and answer questions in the iPLEDGE Program system.

Please select you answer to the question and click Submit.
Please do not use browser’s Refresh, Back or Forward buttons when answering the questions, or you may have to start again.
Comprehension Questions

Correct: You have selected the right answer.

Condoms

If you use a lubricant with a male latex condom, it should be a water-based lubricant.

- True
- False

Finish
Comprehension Questions

Incorrect Answer: The correct answer is
"Continue to use 2 effective methods of birth control together all the time."

General Contraception Requirements

You have finished your last dose of isotretinoin. Your doctor has ordered a pregnancy test. For the next month, you:

- Continue to use 2 effective methods of birth control together all the time.
- Stop using your secondary method because you are not taking isotretinoin.
- Go for the pregnancy test at any time during the month.

Please do not use browser’s Refresh, Back or Forward buttons when answering the questions, or you may have to start again.
Patient – Comprehension Test Results - SAMPLE: Results: Failed

Comprehension Questions Results

- Results: Failed to Demonstrate Comprehension
- You have answered the following questions incorrectly.

Important Note:
If this is your last month of treatment:
- Remember to continue using the two methods of acceptable birth control for 30 days after the last dosage.
- Get a pregnancy test after the last dosage and 30 days after the last dosage.

Question: One goal of iPLEDGE is making sure pregnant women do not take isotretinoin

Answers:
- True
- False

Explanation: The correct answer is True. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.

Reference: The Guide to Isotretinoin For Female Patients Who Can Get Pregnant, What is the iPLEDGE Program (see page 4).

Please review the Educational Materials before you answer the questions again.
Patient – Comprehension Test Results - SAMPLE: Results: Passed
Patient – Contraception Information:

- Safety Information About Isotretinoin
- Birth Control Workbook
- The Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- iPLEDGE Program Birth Control Information Sheet/iPLEDGE Program Checklist
Patient Information

About Patient Information

Are you thinking about starting treatment with isotretinoin? You can learn more about isotretinoin and about the iPLEDGE Program by reading the introductory information brochure and the medication guide available below.

View Information Online

You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.

Patient Information:

- Guide to Isotretinoin for Female Patients Who Can Get Pregnant
- Birth Control Workbooks
- iPLEDGE Program Birth Control Information Sheet/iPLEDGE Program Checklist
- Contraception Counseling Guide and Contraception Referral Form
- Isotretinoin Contraception Referral Form
- Guide to Isotretinoin for Male Patients and Female Patients Who Cannot Get Pregnant
- Safety Information About Isotretinoin
- Dr. Reddy’s Zeranol Medication Guide
- Mylan Amnesteem Medication Guide
- Sun Apremil Medication Guide
- Teva Claravis Medication Guide
- Akorn Myorisan Medication Guide
- Amneal Isotretinoin Medication Guide

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
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<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
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<tr>
<td>Amnesteem®</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1-800-796-9526</td>
</tr>
<tr>
<td>Claravis®</td>
<td>Teva Pharmaceuticals USA, Inc.</td>
<td>1-800-227-7522</td>
</tr>
<tr>
<td>Myorisan™</td>
<td>Akorn, Inc.</td>
<td>1-800-632-5676</td>
</tr>
<tr>
<td>Absorica™</td>
<td>Sun Pharmaceutical Industries, Inc.</td>
<td>1-800-486-7694</td>
</tr>
<tr>
<td>Zenatane™</td>
<td>Dr. Reddy's Laboratories, Ltd.</td>
<td>1-888-375-3784</td>
</tr>
<tr>
<td>Amneal isotretinoin</td>
<td>Amneal Pharmaceuticals, LLC.</td>
<td>1-877-835-5472</td>
</tr>
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About Isotretinoin

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, microtia, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE®. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.
About iPledge

The iPledge Program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a SINGLE pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPledge Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and all male and female patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of reproductive potential. The iPledge Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPledge Program system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of reproductive potential. As part of the ongoing risk management of isotretinoin products. it is crucial that a female of reproductive potential selects and commits to use two methods of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mlU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

Each month, the prescriber must enter the female patient's pregnancy results and the 2 methods of contraception she has been using in the iPledge Program system. The iPledge Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPledge Program system via the internet (www.ipledgeprogram.com), telephone (1-866-495-0654) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.
Patient – Change Primary Prescriber

Change Primary Prescriber

If you change your Primary Prescriber, you will not be able to receive prescriptions from your current prescriber. Instead you will be receiving your future prescriptions from your new prescriber.

Please enter any or all search criteria and click the Search button.

First Name: Jane
Last Name: Smith
Phone:
City:
State: PA
Zip Code:

Search

Found

Name | Address | Contact
--- | --- | ---
Jane Smith | Blue Bell, PA | 215-254-2546

Showing 1 to 1 of 1 entries

1 | 10

To transfer to this prescriber please click the Commit To Transfer button.

Please note: Your transfer will not be complete until your selected prescriber has accepted you as a patient.

Commit To Transfer

iPLEDGE Privacy Notice and Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2016 iPLEDGE
Patient – Find a Participating Pharmacy
Patient – Update My Information

Update My Information

- Change Password
- Change Date of Personal Significance
- Update Contact Information
Patient – Update My Information – Change Password

Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes
Change Date of Personal Significance

Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the Call Center.

All fields below are required unless otherwise indicated.

Password

Date of Personal Significance: (MM/DD/YYYY)

Confirm Date of Personal Significance: (MM/DD/YYYY)

Save Changes
Patient – My Program Status

Name: Jane Smith
Program Status: Qualified to Receive Drug
Action: No patient action is required at this time.

Information: You may obtain your prescription at the pharmacy. You must obtain the prescription before 11:59 PM Eastern Time on the last day of your prescription window.

June 2015

<table>
<thead>
<tr>
<th>Sun</th>
<th>Mon</th>
<th>Tue</th>
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Key
- Today or future day for an active 7 day window
- A past day for a 7 day window
- A 7 day window that has expired without prescription fill
- Action may occur on this date or any date after

You may click on underlined text to perform the required action.
Patient – Safety Notice

SAFETY NOTICE

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.
FDA REMS Submission

Pharmacy Screens Inventory

iPLEDGE Program

Revised: December 2017
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