



iPLEDGE[®]
Committed to Pregnancy Prevention

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

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Wholesaler Product Return Letter (continued)

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: _____ State: _____ 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: _____ State: _____ Zip: _____

Ship to Address: _____ City: _____ State: _____ 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



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Welcome
Have Questions? Call our toll-free number **1-866-495-0654**

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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”



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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.

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, the birth control that you have chosen and the risks associated with isotretinoin. 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.

[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 1-866-495-0654.

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”



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

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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 1-866-495-0654.

A Pregnancy: To report a pregnancy, please call 1-866-495-0654.

Patient – Comprehension Questions- Did not fill Rx in previous window



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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.

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Patient – Comprehension Questions



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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](#)

Patient – Comprehension Questions – Abstinence Confirmation



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Birth Control Verification

All fields listed below are required unless otherwise indicated.

Please select your birth control methods click the **Submit** button.

Primary:

Important Information X

- You have chosen abstinence and agree that you **will not have sex** or sexual contact with any male, 24 hours a day, 7 days a week. If you cannot commit completely to not having sex (abstinence) while taking isotretinoin you **MUST** contact your prescriber before engaging in sexual activity.
- One of the most common reasons that women get pregnant is that they engage in sexual activity when they have planned to be abstinent.

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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



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Birth Control Verification

All fields listed below are required unless otherwise indicated.

Please select your birth control methods click the **Submit** button.

Primary

Secondary

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

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Patient – Comprehension Questions – Primary (First Time):



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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)
- Progesterone-only Mini-pills
- Abstinence

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

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



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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

Hormonal IUD

Non-hormonal IUD

Tubal Sterilization

Male Vasectomy

Natural Family Planning

Hormonal Shot

Hormonal Vaginal Ring

Female Condom

Hormonal Skin Patch

Birth Control Pills (Combination Type)

Progesterone-only Mini-pills

Male Latex Condom

Cervical Cap with a Spermicide

Diaphragm with a Spermicide

Vaginal Sponge

Cervical Shield

Withdrawal

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 – Primary (Subsequent):

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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)
- Progesterone-only Mini-pills
- Abstinence

Submit

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



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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

Hormonal IUD

Non-hormonal IUD

Tubal Sterilization

Male Vasectomy

Natural Family Planning

Hormonal Shot

Hormonal Vaginal Ring

Female Condom

Hormonal Skin Patch

Birth Control Pills (Combination Type)

Progesterone-only Mini-pills

Male Latex Condom

Cervical Cap with a Spermicide

Diaphragm with a Spermicide

Vaginal Sponge

Cervical Shield

Withdrawal

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Comprehension Questions – Sample Question



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Comprehension Questions

Program Steps

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.

Submit

Please select your 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.

Patient – Comprehension Question - Correct Answer - SAMPLE:



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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

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Patient – Comprehension Question - Incorrect Answer - SAMPLE:

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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.

Next

Please do not use browser's Refresh, Back or Forward buttons when answering the questions, or you may have to start again.

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Patient – Comprehension Test Results- SAMPLE: Results: **Failed**



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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.

[Click here to return to the home page](#)

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

Answers:

True

False

Explanation: The correct answer is 1. 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**



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Comprehension Questions Results

- The questions are complete.
- You may obtain your prescription any time before 11:59P.M. Eastern Time on m/d/yyyy

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.

[Click here to return to the home page](#)

Patient – Contraception Information:



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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 – Patient Information



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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 Workbook](#)
- [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 Zenatane Medication Guide](#)
- [Mylan Amnesteem Medication Guide](#)
- [Sun Absorica 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.

Product Name	Company	Phone Number
Amnesteem [®]	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis [®]	Teva Pharmaceuticals USA, Inc.	1-800-227-7522
Myorisan [™]	Akorn, Inc.	1-800-932-5676
Absorica [™]	Sun Pharmaceutical Industries, Inc.	1-800-406-7984
Zenatane [™]	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784
Amneal isotretinoin	Amneal Pharmaceuticals, LLC	1-877-835-5472



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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, micropinna, 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.



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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 mIU/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



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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	MI (Optional)
<input type="text" value="Jane"/>	<input type="text"/>
Last Name	
<input type="text" value="Smith"/>	
Phone	
<input type="text"/>	
City	
<input type="text"/>	
State	Zip Code
<input type="text" value="PA"/>	<input type="text"/>

Search

Found

Name	Address	Contact
Jane Smith	Blue Bell, PA	215-234-2345

Showing 1 to 1 of 1 entries

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

Patient – Find a Participating Pharmacy



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Find a Participating Pharmacy

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

Zip

City

State

Search

Patient – Update My Information



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Update My Information

[Change Password](#)

[Change Date of Personal Significance](#)

[Update Contact Information](#)

Patient – Update My Information – Change Password



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Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes

Patient – Update My Information – Change DOPS



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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 – Update My Information – Update Contact Information



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Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center.

All fields below are required unless otherwise indicated.

First Name MI (Optional)

Last Name

Address

City

State Zip

Phone Number

Fax (Optional)

Email (Optional)

Preferred Method of Communication

Cancel

Save Changes

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Patient 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

Sun	Mon	Tue	Wed	Thu	Fri	Sat
31	1	2	3 If you haven't already, obtain your prescription More...	4 If you haven't already, obtain your prescription More...	5 If you haven't already, obtain your prescription More...	6 If you haven't already, obtain your prescription More...
7 If you haven't already, obtain your prescription More...	8 If you haven't already, obtain your prescription More...	9 If you haven't already, obtain your prescription More...	10 First day you may have your next pregnancy test More...	11	12	13

Key

- Today or future day for an active 7 day window
- A 7 day window that has expired without prescription fill
- A past day for a 7 day window
- Action may occur on this date or any date after

You may click on underlined text to perform the required action.



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Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

- A. [TECHNICAL ASSISTANCE](#)
- B. [PATIENT](#)
- C. [ALL USERS](#)



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iPLEDGE Privacy Notice and Terms of Use

iPLEDGE Privacy Notice and Terms of Use

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at <http://www.ipledgeprogram.com> (the "Site"). The "iPLEDGE Website" is a Registered User-only account portal available through the Site which enables Registered Users to participate with 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.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"Registered Users" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "Patients" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program. "Prescribers" are prescribers that prescribe restricted distribution drugs pursuant to the iPLEDGE Program. "Designated Agents" are persons designated by Prescribers to act on their behalf with the iPLEDGE Website. Pharmacists are pharmacists that utilize the iPLEDGE Website to verify a patient's enrollment in iPLEDGE and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site ("you" or "your") and the sponsors of the Site ("iPLEDGE" "we", "us" and "our").

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Access to and use of the Site is conditioned upon your assent to these Terms of Use. You are deemed to have assented to these Terms of Use when you use any available page of the Site. You are deemed to have assented to these Terms of Use as applicable to the iPLEDGE Website, when you complete the online registration processes required for Registered Users and indicate during the registration process that you accept these Terms of Use along with the Privacy Policy incorporated therein. You are deemed to have accepted these Terms of Use each time you access the Site and each time you use your login credentials to access the iPLEDGE Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these Terms of Use. These Terms of Use and the Privacy Policy are available during registration for the iPLEDGE Website and on various pages of the Site.

UPDATES

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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.

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

FDA REMS Submission

Pharmacy Screens Inventory

iPLEDGE Program

Revised: December 2017

Pharmacy Screens Inventory:

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