

Be Aware Video Script

Opening Segment

“ISOTRETINOIN CANNOT BE TAKEN BY WOMEN WHO ARE PREGNANT, BECAUSE ISOTRETINOIN CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY.

In this video we will see what can happen to an unborn baby if the baby’s mother takes isotretinoin.

A woman must not take isotretinoin at any time during pregnancy.

Storyboard P2

Isotretinoin is usually prescribed for males and females to treat the most severe form of acne called nodular acne. This type of acne cannot be cleared up by any other acne treatments, including antibiotic pills. Nodular acne has many red, swollen, tender lumps that form in the skin. These lumps are the size of a pencil eraser or larger and can result in permanent scars if not treated.

Because of serious side effects and birth defects, patients should use isotretinoin only if other treatments including antibiotic pills have not worked.

Storyboard P3

“FEMALE PATIENTS MUST NOT TAKE ISOTRETINOIN IF THEY ARE PREGNANT, PLAN TO BECOME PREGNANT OR BECOME PREGNANT DURING THERAPY. TO AVOID PREGNANCY, WOMEN MUST USE TWO FORMS OF EFFECTIVE CONTRACEPTION ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE TAKING ISOTRETINOIN, AND FOR ONE MONTH AFTER STOPPING ISOTRETINOIN UNLESS THEY ARE ABSOLUTELY ABSTINENT, NEVER HAVING SEX, OR HAVE HAD THEIR UTERUS OR WOMB REMOVED”.

Storyboard P4

“ISOTRETINOIN CAPSULES BREAK DOWN IN THE BODY AND THE MEDICINE ENTERS INTO THE BLOODSTREAM

Storyboard P5

“AND THE BLOOD IS CARRIED INTO THE PLACENTA WHERE IT REACHES THE UNBORN FETUS.

The medicine can cause severe birth defects.”

Storyboard P6

“It is highly possible that the unborn baby may die because the baby’s mother took isotretinoin.”

Storyboard P7

“If the fetus lives, as the fetus develops, several birth defects can begin to take place.

These birth defects may be caused by taking isotretinoin during pregnancy”.

Storyboard P8

“One of these birth defects may be abnormal skull development”. “Use of isotretinoin during pregnancy may cause an under development or over development of the skull”.

Storyboard P9

“Development of the ears may also be affected”. “The ears may not fully develop if isotretinoin is used during pregnancy. The outer ear may be deformed and the ear canal may be very small or absent entirely causing deformity”.

Storyboard P10

“The eyes also may not develop fully”.

“The eye socket may be very small or not develop at all causing facial deformity

Storyboard P11

“As face structure begins to form the fetus can have a flattening of the nose and a twisting of the mouth. These birth defects could happen from using isotretinoin during pregnancy”.

Storyboard P12

“The baby may also be born with a separation of the roof of the mouth and sometimes the lips which is known as a cleft palate”.

Storyboard P13

IN ADDITION TO THE VISIBLE DEFECTS, SEVERAL INTERNAL SERIOUS AND LIFE-THREATENING BIRTH DEFECTS MAY DEVELOP IN THE HEART AND IN THE ENTIRE HEART AND BLOOD FLOW SYSTEM.

One of these defects can include an abnormal heart that has the arteries and veins in the wrong position.

Storyboard P14

“The system that helps to fight infection may also be affected. One of the glands in this system - the thymus gland may not develop and the baby then would have trouble fighting infections.” “In addition, another gland -the parathyroid gland may not develop. The parathyroid gland helps the baby to form bones by controlling the amount of calcium in the body.

Storyboard P15

Brain and nervous system defects including an abnormal brain may occur...” OR AN UNDERDEVELOPMENT OF THE BRAIN. IT HAS ALSO BEEN REPORTED THAT SOME CHILDREN HAVE LOW IQ SCORES”.

Storyboard P17

In summary, taking isotretinoin during pregnancy can result in any or all of these birth defects:

The skull may over- or under- develop.

FACIAL DYSMORPHIA CAN OCCUR, CAUSING A FLATTENING OF THE NOSE AND DISTORTION OF FACIAL STRUCTURE.

Enlargement of the brain may occur.

Eye sockets may be very small or not develop at all.

The brain can also under-develop.

Ears may not fully develop.

The thymus gland may not develop, affecting an infant's ability to fight off disease.

Abnormalities in the heart and entire cardiac system can be life threatening.

A cleft palate may form.

Storyboard P18

UNLIKE THE BIRTH DEFECTS THAT ARE SEEN IN THE BABIES WHEN MOTHERS TAKE ISOTRETINOIN, THERE IS NO PATTERN OF BIRTH DEFECTS WHEN FATHERS TAKE ISOTRETINOIN.

“But men who take isotretinoin should be careful in other ways.” Men might not realize that they should not donate blood during, and for a period of one month following, the end of their isotretinoin treatment”.

Storyboard P19

“As discussed earlier, isotretinoin is carried through the bloodstream and a pregnant woman could, unknowingly accept a blood transfusion from a man or a woman who took isotretinoin. The blood and medicine could then pass into the placenta possibly harming an unborn baby”.

Therefore, it is extremely important that both men and women taking isotretinoin do not donate blood during treatment and for a period of at least one month following the end of their isotretinoin treatment.

Storyboard P20

“Neither men nor women should *ever* share their isotretinoin with another woman...”

Storyboard P21

“...BECAUSE OF THE RISK THAT SHE MAY BE PREGNANT.”

“No one should ever share any medicine with anyone else, because the medicine may harm the other person.”

Black Box

YOU MUST NOT BECOME PREGNANT WHILE TAKING ISOTRETINOIN, OR FOR ONE MONTH AFTER YOU STOP TAKING ISOTRETINOIN.

Isotretinoin can cause severe birth defects in babies of women who take it while they are pregnant, even if they take isotretinoin for only a short time.

There is an extremely high risk that your baby will be deformed or will die if you are pregnant while taking isotretinoin. Taking isotretinoin also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for isotretinoin unless there is proof they have had two negative pregnancy tests. The first test must be done when your prescriber decides to prescribe isotretinoin. The second pregnancy test must be done during the first five days of the menstrual period right before starting isotretinoin therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for isotretinoin unless there is proof that they have had a negative pregnancy test.

WHILE YOU ARE TAKING ISOTRETINOIN, YOU MUST USE EFFECTIVE BIRTH CONTROL. YOU MUST USE 2 SEPARATE, EFFECTIVE FORMS OF BIRTH CONTROL AT THE SAME TIME FOR AT LEAST ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE YOU TAKE IT, AND FOR ONE MONTH AFTER YOU STOP TAKING IT. YOU CAN EITHER DISCUSS EFFECTIVE BIRTH CONTROL METHODS WITH YOUR PRESCRIBER OR GO FOR A FREE VISIT TO DISCUSS BIRTH CONTROL WITH ANOTHER PHYSICIAN OR FAMILY PLANNING EXPERT. YOUR PRESCRIBER CAN ARRANGE THIS FREE VISIT, WHICH WILL BE PAID FOR BY THE MANUFACTURER.

You must use two separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons that you would not need to use 2 separate methods of effective birth control:

- 1. You have had your womb removed by surgery– a hysterectomy or
- 2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during and for one month after isotretinoin treatment.

IF YOU HAVE SEX AT ANY TIME WITHOUT USING TWO FORMS OF EFFECTIVE BIRTH CONTROL, GET PREGNANT, OR MISS YOUR PERIOD, STOP USING ISOTRETINOIN AND CALL YOUR PRESCRIBER RIGHT AWAY.

Be Prepared, Be Protected

VIDEO SCRIPT

SCENE 1: ABSTINENCE

FEMALE 1: I thought I was abstinent. I guess I didn't know what abstinence really means. Now I do.

ANNOUNCER: It's important to know what abstinence means. Not having sex. Not once, twice, or ever. Just because you're not having sex now, doesn't mean you will have always be abstinent. You're only abstinent if you know you won't be tempted to have sex. And this becomes especially important when you are taking a drug that may cause birth defects to your unborn baby. Think about it: Are you *really* abstinent?

SCENE 2: UNPREPARED PREGNANCY

FEMALE 2: I can't believe I'm pregnant. It was just that one time. And I have been so careful. This can't be right.

ANNOUNCER: You have to be sure if you are having sex at any time you can't use any excuses. It doesn't matter if your periods are irregular, or if you think you can't get pregnant, or if you don't have sex frequently. And if you are on a medication that could be harmful to your unborn baby, you need to be especially and extremely careful. Once can be enough.

SCENE 3: WITHDRAWAL

FEMALE 3: We used withdrawal for a long time. But this time withdrawal just didn't work.

ANNOUNCER: Withdrawal is unreliable. Use effective birth control such as the contraceptive pill, diaphragm, condom, and if you are taking a medication that may cause birth defects to your unborn baby, use a combination of two. If you don't like the pill, you have other options such as long lasting contraceptive implants, injectables, and intrauterine devices—IUDs. Always practice safe birth control using reliable effective methods to avoid pregnancy.

SCENE 4: BEING UNPREPARED

FEMALE 4: This is so nice. (Thoughts of Female 4) *I didn't think this would happen. I mean at least not tonight. I'm so surprised and unprepared.*

ANNOUNCER: Be prepared and protected. Think about it before hand. You may have sex and you might get pregnant? Don't assume your partner will take responsibility. And if you are on a medication that may cause birth defects—think about your unborn baby. Be prepared and ready to use reliable effective forms of birth control.

SCENE 5: BIRTH CONTROL CAN FAIL

FEMALE 5: I can't believe this. There's a hole in my diaphragm. What if I get pregnant? What am I going to do?

ANNOUNCER: Your doctor or nurse can help you find out if you are really pregnant. If you are, they can give you advice. Always make sure your birth control is reliable and effective. And if you are on a drug that may cause birth defects, be sure you are doubly protected.

If you have any questions you should speak to your doctor or nurse. Carefully follow instructions provided by your prescriber, and consult with them if you have any questions about pregnancy, birth control, or your medical treatment.

[TYPE—NO VOICE]

Frame 1:

Complete Contraceptive Certainty = Be prepared Be protected

Frame 2:

You have just seen five scenarios with the most common reasons women have unwanted or ill-timed pregnancies.

Frame 3:

If you are not being completely abstinent, then

- Use birth control regularly
- Use the most effective types of birth control
- Be sure the method you choose is reliable
- Be prepared and be protected

Frame 4:

Brought to you as an educational service.



FDA REMS Submission

Patient Screens Inventory

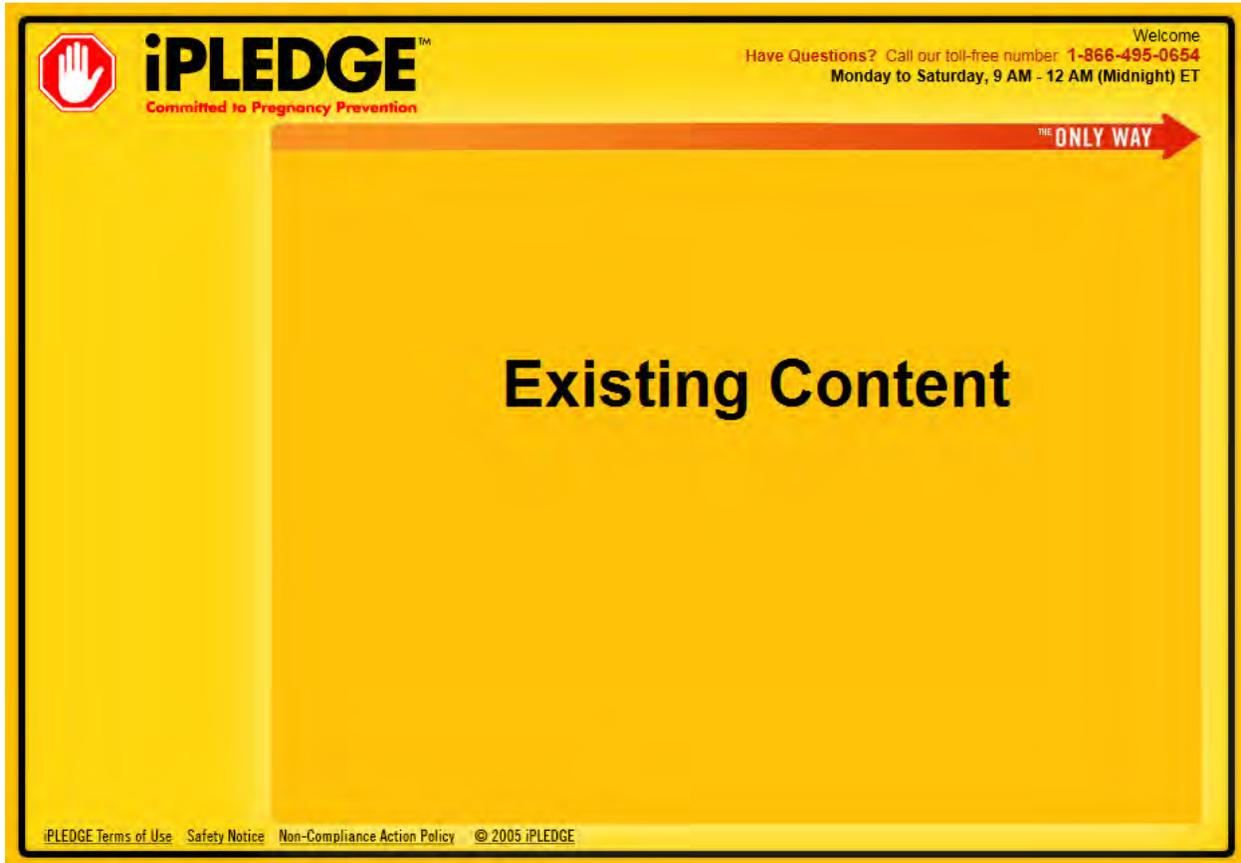
iPLEDGE Program

Revised: May 2016

Patient Screens Inventory:

- Common – Header and Footer
- Patient Registration – from Public Home Page
- Patient Home Page
- Comprehension Questions
- Contraception Information
- Patient Information
- About Isotretinoin
- About iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs/How To's
- Terms of Use
- Safety Notice

Common – iPLEDGE Web page header/footer



The image shows a template for the iPLEDGE web page header and footer. The header is yellow and contains the iPLEDGE logo (a red hand icon) and the text "iPLEDGE™ Committed to Pregnancy Prevention". To the right, it says "Welcome" and "Have Questions? Call our toll-free number: 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow points to the right with the text "THE ONLY WAY". The main content area is a large yellow rectangle with the text "Existing Content" in the center. The footer is a thin yellow bar at the bottom with the text "iPLEDGE Terms of Use Safety Notice Non-Compliance Action Policy © 2005 iPLEDGE".

Patient Registration from Public Home Page

Welcome
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

iPLEDGE™
Committed to Pregnancy Prevention

THE ONLY WAY

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.

[HOME](#)

[PATIENT INFORMATION](#)

[ABOUT ISOTRETINOIN](#)

[ABOUT iPLEDGE](#)

[PRESCRIBER INFORMATION](#)

[Find a Participating Pharmacy](#)

[FAQs / How to's](#)

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient Home Page for Patient in Program Status “Required to Demonstrate Comprehension”



Welcome iPLEDGE Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

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.

Answer the Comprehension Questions

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 .

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

Patient Home Page for Patient Not in Program Status “Required to Demonstrate Comprehension”

The screenshot shows the iPLEDGE patient home page. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". To the right, it says "Welcome iPLEDGE Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow points to the right with the text "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT iPLEDGE. Below these are links for "Change Primary Prescriber", "Find a Participating Pharmacy", "Update My Information", "My Program Status", and "FAQs / How to's".

The main content area features a "SAFETY NOTICE" section with the following text:

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.

Below the safety notice is a "Check My Program Status" section with a "My Program Status" button. Underneath is a "How to Report" section with the following text:

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 .

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 iPLEDGE".

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

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". To the right, it says "Welcome iPLEDGE Patient" with a "Logout" link. Below that, it provides a toll-free number: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow points to the right with the text "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT iPLEDGE. Below these are links for "Change Primary Prescriber", "Find a Participating Pharmacy", "Update My Information", "My Program Status", and "FAQs / How to's".

The main content area is titled "Answer Your Questions". It features a section titled "Before You Get Started" with the following text: "iPLEDGE has no record of you filling a prescription in your prescription window from Oct 29, 2009 through Nov 4, 2009. Did you fill your prescription during this prescription window?". There are two radio button options: "Yes" and "No". Below the options is a note: "Note: Your answer will not restrict you from getting your prescription." and a "Submit" button.

A reminder text at the bottom of the section states: "Reminder: Please be sure that your prescriptions are authorized in the iPLEDGE system by the Pharmacy. If the Pharmacy does not authorize the prescription in the iPLEDGE 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 sticker on your prescription bag. You may find a participating Pharmacy by using the Find a Pharmacy feature on the iPLEDGE website."

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", "Non-Compliance Action Policy", and "© 2005 iPLEDGE".

Patient – Comprehension Questions

**iPLEDGE™**
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient [Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

-  HOME
-  **COMPREHENSION QUESTIONS**
-  CONTRACEPTION INFORMATION
-  PATIENT INFORMATION
-  ABOUT ISOTRETINOIN
-  ABOUT iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

Answer Your Questions

Please follow these two steps to demonstrate iPLEDGE Program comprehension.

Step 1: Birth Control Verification

Please enter the two forms of birth control that you are using. These must be the same two forms 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 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 pick up your prescription once you have correctly answered these questions.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Comprehension Questions - Abstinence pop-up message



iPLEDGE™

Committed to Pregnancy Prevention

Welcome iPLEDGE Patient

[Logout](#)

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

Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary *

Abstinence

Barrier/Primary *

More Information

Abstinence means that you will not have sex or sexual physical contact with any male 24 hours a day, 7 days a week. This can be hard to do. It is not a recommended way to prevent pregnancy for the iPLEDGE Program. One of the most common causes of unplanned pregnancy is failing to maintain abstinence (not being able to avoid sex).

You should really think about using birth control, even if you have never had sex – even if you are absolutely 100% certain you will not have any sexual contact with any male before, during and for 1 month after taking isotretinoin. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.

HOME

COMPREHENSION QUESTIONS

CONTRACEPTION INFORMATION

PATIENT INFORMATION

ABOUT ISOTRETINOIN

ABOUT iPLEDGE

Change Primary Prescriber

Find a Participating Pharmacy

Update My Information

My Program Status

FAQs / How to's

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Comprehension Questions – (after patient closes pop-up, and selects Abstinence as primary method) – Abstinence Confirmation

Welcome iPLEDGE Patient
[Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

iPLEDGE™
Committed to Pregnancy Prevention

THE ONLY WAY

Birth Control Verification

* denotes required field
Please select your contraception methods click the Submit button.

Primary *

Barrier/Primary *

Important Information

- 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.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

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

 **iPLEDGE™**
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Birth Control Verification

** denotes required field*
Please select your contraception methods click the Submit button.

Primary *

Barrier/Primary *

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 iPLEDGE Program Isotretinoin Educational Kit For Female Patients Who Can Get Pregnant? *

Yes No

If yes, did you read

1. The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant? *
 Yes No
2. The iPLEDGE Program 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

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Comprehension Questions – Primary (First Time):

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient
[Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

Birth Control Verification

** denotes required field*
Please select your contraception methods click the Submit button.

Primary *
Barrier/Primary *
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

Did you receive the iPLEDGE Patient Education Program? *

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

Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

Privacy Statement | Safety Notice | Non-Compliance Action Policy | © 2005 iPLEDGE

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

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

Birth Control Verification

** denotes required field*
Please select your contraception methods click the Submit button.

Primary *

Barrier/Primary *

Did your doctor or anyone in your family advise you not to become pregnant while taking isotretinoin? *
 Yes No

Did you receive the iPLEDGE Pregnancy Video? *
 Yes No

Did you watch the video, "Be Informed About Isotretinoin" about the effects of isotretinoin? *
 Yes No

Did your doctor or anyone in your family advise you not to become pregnant while taking isotretinoin? *
 Yes No

From whom did you receive birth control counseling? *

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

Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

Privacy Statement | Safety Notice | Non-Compliance Action Policy | © 2005 iPLEDGE

Patient – Comprehension Questions – Primary (Subsequent):

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPLEDGE Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow graphic on the right says "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT iPLEDGE. Below these are links for "Change Primary Prescriber", "Find a Participating Pharmacy", "Update My Information", "My Program Status", and "FAQs / How to's".

The main content area is titled "Birth Control Verification". It includes a note: "* denotes required field" and "Please select your contraception methods click the Submit button." There are two dropdown menus: "Primary *" and "Barrier/Primary *". The "Primary *" dropdown is open, showing a list of options: Birth Control Pills, IUD Progesterone T, Hormonal Skin Patch, Hormonal Vaginal Ring, Hormone Shot, Natural Family Planning, IUD, Under-the-skin Hormonal Implants, Tubal Sterilization, Progesterone-only Mini-pills, Partner's Vasectomy, and Abstinence. A "Submit" button is located below the dropdowns.

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 iPLEDGE".

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

The screenshot displays the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPLEDGE Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow on the right points to the text "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, ABOUT iPLEDGE, Change Primary Prescriber, Find a Participating Pharmacy, Update My Information, My Program Status, and FAQs / How to's.

The main content area is titled "Birth Control Verification". It includes a note: "* denotes required field" and "Please select your contraception methods click the Submit button." There are two dropdown menus: "Primary *" with "Birth Control Pills" selected, and "Barrier/Primary *". A "Submit" button is located below the dropdowns. A list of contraception methods is shown in a scrollable area:

- IUD Progesterone T
- Hormonal Skin Patch
- Hormonal Vaginal Ring
- Hormone Shot
- Natural Family Planning
- IUD
- Under-the-skin Hormonal Implants
- Tubal Sterilization
- Progesterone-only Mini-pills
- Partner's Vasectomy
- Fertility Awareness
- Male Latex Condom
- Female Condom
- Diaphragm
- Cervical Cap
- Withdrawal
- Vaginal Sponge
- Cervical Shield

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 iPLEDGE".

Comprehension Questions – Sample Question



iPLEDGETM
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient

[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

-  HOME
-  COMPREHENSION QUESTIONS
-  CONTRACEPTION INFORMATION
-  PATIENT INFORMATION
-  ABOUT ISOTRETINOIN
-  ABOUT iPLEDGE

- [Change Primary Prescriber](#)
- [Find a Participating Pharmacy](#)
- [Update My Information](#)
- [My Program Status](#)
- [FAQs / How to's](#)

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 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.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Comprehension Question - Correct Answer - SAMPLE:

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPLEDGE Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow graphic points to the right with the text "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT iPLEDGE. Below these are links for "Change Primary Prescriber", "Find a Participating Pharmacy", "Update My Information", "My Program Status", and "FAQs / How to's".

The main content area is titled "Comprehension Questions:". The question is "Condoms". The text of the question is "If you use a lubricant with a latex condom, it should be a water-based lubricant." Below the question are two radio button options: "True" (which is selected) and "False". A yellow box on the right contains the message "Correct. You have selected the right answer." Below the question is a green "Finish" button.

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", followed by the copyright notice "© 2005 iPLEDGE".

Patient – Comprehension Question - Incorrect Answer - SAMPLE:

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient
[Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

Comprehension Questions:

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 forms of birth control together all the time.
- Stop using your secondary form because you are on isotretinoin.
- Go for the pregnancy test at any time during the month.

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

[Next →](#)

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

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

HOME
COMPREHENSION QUESTIONS
CONTRACEPTION INFORMATION
PATIENT INFORMATION
ABOUT ISOTRETINOIN
ABOUT iPLEDGE
Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

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

The screenshot displays the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". To the right, it says "Welcome iPLEDGE Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow graphic points to the right with the text "THE ONLY WAY".

The left sidebar contains navigation links: HOME, COMPREHENSION QUESTIONS (highlighted), CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT iPLEDGE. Below these are links for "Change Primary Prescriber", "Find a Participating Pharmacy", "Update My Information", "My Program Status", and "FAQs / How to's".

The main content area is titled "Comprehension Questions Results". It contains a red-bordered box with the following text:

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

Below this is an "Important Note" section: "If this is your last month of treatment:" followed by a bulleted list:

- Remember to continue using the two forms 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.

A link "Click here to return to home page" is provided. The "Question" section states: "Question: One goal of iPLEDGE is making sure pregnant women do not take isotretinoin". The "Answers" section shows "True" with a green checkmark and "False" with a red X. The "Explanation" states: "The correct answer is 1. True. The iPLEDGE Program goal is preventing pregnancy and birth defects. iPLEDGE tries to make sure that a woman who begins treatment with isotretinoin is not pregnant and will not become pregnant while being treated and for 1 month after last dose." The "Reference" is: "The iPLEDGE Program Guide to Isotretinoin for Female Patients Who Can Get Pregnant, ABOUT Isotretinoin (see page 2)."

At the bottom of the main content area, it says: "Please review the Educational Materials before you answer the questions again."

The footer contains links for "Privacy Statement", "Safety Notice", "Non-Compliance Action Policy", and "© 2005 iPLEDGE".

Patient – Comprehension Test Results- SAMPLE:
Results: Passed

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline 'Committed to Pregnancy Prevention'. To the right, it says 'Welcome iPLEDGE Patient' with a 'Logout' link and contact information: 'Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET'. A red arrow graphic points to the right with the text 'THE ONLY WAY'. The main content area is titled 'Comprehension Questions Results' and contains a green-bordered box with two bullet points: 'The questions are complete.' and 'You may obtain your prescription any time before 11:59 P.M. Eastern Time on 6/9/2015'. Below this is an 'Important Note' section with the text 'If this is your last month of treatment:' followed by two bullet points: 'Remember to continue using the two forms of acceptable birth control for 30 days after the last dosage.' and 'Get a pregnancy test after the last dosage and 30 days after the last dosage.' At the bottom of the main area is a link: 'Click here to return to home page'. On the left side, there is a vertical navigation menu with icons and text for: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, and ABOUT IPLEDGE. Below the menu are links for 'Change Primary Prescriber', 'Find a Participating Pharmacy', 'Update My Information', 'My Program Status', and 'FAQs / How to's'. At the very bottom of the page, there are links for 'Privacy Statement', 'Safety Notice', 'Non-Compliance Action Policy', and '© 2005 IPLEDGE'.

Patient – Contraception Information:

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPledge Patient" with a "Logout" link, and provides a toll-free number "1-866-495-0654" available Monday to Saturday, 9 AM - 12 AM (Midnight) ET. A red arrow graphic on the right side of the header points to the right and contains the text "THE ONLY WAY".

The left sidebar contains a navigation menu with the following items:

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT IPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

The main content area is titled "Contraception Information" and contains a list of links:

- [Isotretinoin and Birth Defects](#)
- [Sex, Pregnancy and Birth Control](#)
- [Different Methods of Birth Control](#)
- [Emergency Contraception](#)
- [Pregnancy and Pregnancy Testing](#)

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", "Non-Compliance Action Policy", and "© 2005 IPLEDGE".

Patient – Patient Information



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

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:

- [The iPLEDGE Program Patient Introductory Brochure](#)
- [Mylan Amnesteem Medication Guide](#)
- [Teva Claravis Medication Guide](#)
- [Ranbaxy Sotret Medication Guide](#)
- [VersaPharm Myorisan Medication Guide](#)
- [Ranbaxy Absorica Medication Guide](#)
- [Dr. Reddy's Zenatane Medication Guide](#)
- [The iPLEDGE Program Guide to Isotretinoin For Female Patients Who Can Get Pregnant](#)
- [The iPLEDGE Program Guide to Isotretinoin For Male Patients and Female Patients Who Cannot Get Pregnant](#)
- [The iPLEDGE Program Birth Control Workbook](#)
- [The iPLEDGE Program Contraception Referral Form and Contraception Counseling Guide](#)
- [Isotretinoin Contraception Referral Form](#)
- [Patient Flowchart](#)

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.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc.	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient - About Isotretinoin

**iPLEDGE™**
Committed to Pregnancy Prevention

Welcome iPledge Patient
[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

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.

[HOME](#)

[COMPREHENSION QUESTIONS](#)

[CONTRACEPTION INFORMATION](#)

[PATIENT INFORMATION](#)

[ABOUT ISOTRETINOIN](#)

[ABOUT IPLEDGE](#)

[Change Primary Prescriber](#)

[Find a Participating Pharmacy](#)

[Update My Information](#)

[My Program Status](#)

[FAQs / How to's](#)

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 IPLEDGE

Patient - About iPLEDGE



iPLEDGE™

Committed to Pregnancy Prevention

Welcome iPledge Patient

[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

- [HOME](#)
- [COMPREHENSION QUESTIONS](#)
- [CONTRACEPTION INFORMATION](#)
- [PATIENT INFORMATION](#)
- [ABOUT ISOTRETINOIN](#)
- [ABOUT iPLEDGE](#)

[Change Primary Prescriber](#)

[Find a Participating Pharmacy](#)

[Update My Information](#)

[My Program Status](#)

[FAQs / How to's](#)

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 childbearing 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 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 childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms 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.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Change Primary Prescriber



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

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	Last Name	Phone
<input type="text" value="iPLEDGE"/>	<input type="text" value="Prescriber"/>	<input type="text"/>
<input type="text" value="City"/>	<input type="text" value="State"/>	<input type="text" value="Zip Code"/>
	<input type="text" value="PA"/> ▼	<input type="text"/>

Found:

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.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

Patient – Find a Participating Pharmacy

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPledge Patient
[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

Find a Participating Pharmacy

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

Zip City State

[HOME](#)
[COMPREHENSION QUESTIONS](#)
[CONTRACEPTION INFORMATION](#)
[PATIENT INFORMATION](#)
[ABOUT ISOTRETINOIN](#)
[ABOUT iPLEDGE](#)
[Change Primary Prescriber](#)
[Find a Participating Pharmacy](#)
[Update My Information](#)
[My Program Status](#)
[FAQs / How to's](#)

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Update My Information

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPledge Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow points to the right with the text "THE ONLY WAY".

The left sidebar contains a navigation menu with the following items:

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT IPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

The main content area is titled "Update My Information" and contains three links:

- [Change Password](#)
- [Change Date of Personal Significance](#)
- [Update Contact Information](#)

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 IPLEDGE".

Patient – Update My Information – Change Password

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". At the top right, it says "Welcome iPledge Patient" with a "Logout" link, and provides a toll-free number "1-866-495-0654" available Monday to Saturday, 9 AM - 12 AM (Midnight) ET. A red arrow graphic points to the right with the text "THE ONLY WAY".

The main content area is titled "Change Password" and contains three input fields: "Old Password", "New Password", and "Confirm New Password". Each field has an asterisk to its right, indicating it is a required field. Below the fields is a "Save Changes" button.

A left-hand navigation menu includes the following items: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, ABOUT IPLEDGE, Change Primary Prescriber, Find a Participating Pharmacy, Update My Information, My Program Status, and FAQs / How to's.

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 IPLEDGE".

Patient – Update My Information – Change DOPS



iPLEDGE™

Committed to Pregnancy Prevention

Welcome iPledge Patient

[Logout](#)

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

Monday to Saturday, 9 AM - 12 AM (Midnight) ET

-  HOME
-  COMPREHENSION QUESTIONS
-  CONTRACEPTION INFORMATION
-  PATIENT INFORMATION
-  ABOUT ISOTRETINOIN
-  ABOUT iPLEDGE

- [Change Primary Prescriber](#)
- [Find a Participating Pharmacy](#)
- [Update My Information](#)
- [My Program Status](#)
- [FAQs / How to's](#)

THE ONLY WAY 

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.

** denotes required field*

Password: *

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

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

[iPLEDGE Terms of Use](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – Update My Information – Update Contact Information



iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPledge Patient [Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Update Contact Information

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

** denotes required field*

First Name*	Last Name*	Middle Initial
<input type="text" value="iPledge"/>	<input type="text" value="Patient"/>	<input type="text" value="O"/>

Address*

City*	State*	Zip*
<input type="text" value="Blue Bell"/>	PA <input type="text"/>	<input type="text" value="19422"/>

Phone Number *	Email *
<input type="text" value="555-555-5555"/>	<input type="text" value="girija.doddapaneni@ubc.com"/>

Preferred method of communication

Email

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – My Program Status



iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient [Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

HOME

COMPREHENSION QUESTIONS

CONTRACEPTION INFORMATION

PATIENT INFORMATION

ABOUT ISOTRETINOIN

ABOUT iPLEDGE

[Change Primary Prescriber](#)

[Find a Participating Pharmacy](#)

[Update My Information](#)

[My Program Status](#)

[FAQs / How to's](#)

Patient Program Status

Prescriber: [iPledge Prescriber \(Change Primary Prescriber\)](#)

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

<input type="checkbox"/> Today or future day for an active 7 day window	<input type="checkbox"/> A past day for a 7 day window
<input type="checkbox"/> A 7 day window that has expired without prescription fill	<input type="checkbox"/> Action may occur on this date or any date after

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

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – FAQs/How To's

The screenshot shows the iPLEDGE Patient website interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". To the right, it says "Welcome iPledge Patient" with a "Logout" link and contact information: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow graphic points to the right with the text "THE ONLY WAY".

The left sidebar contains a navigation menu with the following items:

- HOME
- COMPREHENSION QUESTIONS
- CONTRACEPTION INFORMATION
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs / How to's

The main content area is titled "Frequently Asked Questions (FAQ)" and is divided into two sections:

- iPLEDGE PROGRAM (click topics below for more information)**
 - A. [TECHNICAL ASSISTANCE](#)
 - B. [PATIENT](#)
 - C. [ALL USERS](#)
- HOW TO'S (click topics below for more information)**
 - A. [NON-COMPLIANCE](#)

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 iPLEDGE".

Patient – FAQs/How To's



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Frequently Asked Questions (FAQ)

- **How can I login using my telephone?**

To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system will ask you to indicate which type of user you are (prescriber, patient, pharmacy or designee) and then prompt you to enter your user ID followed by the # button. You may be presented with additional prompts to confirm your user id.

For each character of your username, press the key on the touch pad that corresponds to the number or letter. For example, the 2 button on the phone is used to enter either the number 2 or the letters A, B and C. The # must be pressed after all characters have been entered.

For example, if your username is 12345, type 12345# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 2512345#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.
- B. [PATIENT](#)
- C. [PHARMACY](#)
- D. [PRESCRIBER](#)
- E. [ALL USERS](#)

HOW TO'S (click topics below for more information)

- A. [NON-COMPLIANCE](#)

Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – FAQs/How To's



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

- A. [TECHNICAL ASSISTANCE](#)
- B. [PATIENT](#)
 - [How do I register with the iPLEDGE Program and receive my username and password?](#)
 - [I either lost or forgot my password. How do I reset my password?](#)
 - [How do I update my information?](#)
 - [Why are males included in the iPLEDGE Program?](#)
 - [Why can't I answer my comprehension questions?](#)
 - [How can I find what is left to be completed before I am "Qualified to Receive Drug"?](#)
 - [At what date and time does my prescription window close?](#)
 - [Where do I find a list of local pharmacies that participate in the iPLEDGE Program?](#)
 - [What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?](#)
- C. [PHARMACY](#)
- D. [PRESCRIBER](#)
- E. [ALL USERS](#)

HOW TO'S (click topics below for more information)

- A. [NON-COMPLIANCE](#)

[Change Primary Prescriber](#)
[Find a Participating Pharmacy](#)
[Update My Information](#)
[My Program Status](#)
[FAQs / How to's](#)

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – FAQs/How To's



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Frequently Asked Questions (FAQ)

- At what date and time does my prescription window close?

Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may obtain your prescription. Patients will be provided with a message that states the ending date and time to obtain their prescription. This message has been updated to give patients the exact date and time when their prescription window will close. For example, the message will read:

“You may obtain your prescription anytime before 11:59 PM Eastern Time on 11/21/2015.”

Users using the automated phone system will hear the same message. Patients that are “Qualified to Receive Drug” may also use the “Program Status” feature to verify the ending date and time to obtain their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

Prescribers, patients, and pharmacies can obtain a list of pharmacies using the “Find A Participating Pharmacy” feature.
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

C. [PHARMACY](#)
D. [PRESCRIBER](#)
E. [ALL USERS](#)

HOW TO'S (click topics below for more information)

[Change Primary Prescriber](#)
[Find a Participating Pharmacy](#)
[Update My Information](#)
[My Program Status](#)
[FAQs / How to's](#)

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Patient – FAQs/How To's

The screenshot shows the iPLEDGE patient portal interface. At the top left is the iPLEDGE logo with the tagline "Committed to Pregnancy Prevention". To the right, it says "Welcome iPledge Patient" and includes a "Logout" link. Below this, contact information is provided: "Have Questions? Call our toll-free number 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET". A red arrow graphic on the right side points to the right with the text "THE ONLY WAY".

The left sidebar contains a navigation menu with the following items: HOME, COMPREHENSION QUESTIONS, CONTRACEPTION INFORMATION, PATIENT INFORMATION, ABOUT ISOTRETINOIN, ABOUT IPLEDGE, Change Primary Prescriber, Find a Participating Pharmacy, Update My Information, My Program Status, and FAQs / How to's.

The main content area is titled "Frequently Asked Questions (FAQ)" and features a scrollable list of questions. The first question is: "How can I find what is left to be completed before I am 'Qualified to Receive Drug'?" The answer states that the iPLEDGE system provides updated information on the patient's status and next steps. The second question is: "At what date and time does my prescription window close?" The third question is: "Where do I find a list of local pharmacies that participate in the iPLEDGE Program?" The fourth question is: "What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?" The answer explains that patients should contact the pharmacy to ensure they have enough product and can dispense it within the window. Below the questions is a section titled "HOW TO'S (click topics below for more information)" with a partially visible link for "A. NON-COMPLIANCE".

At the bottom of the page, there are links for "Privacy Statement", "Safety Notice", and "Non-Compliance Action Policy", along with the copyright notice "© 2005 IPLEDGE".

Patient – FAQs/How To's



Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

Frequently Asked Questions (FAQ)

E. ALL USERS

- **Does the iPLEDGE Program have a Privacy Statement?**
Yes. Everyone who wants to take the prescription medication isotretinoin is required to register and participate in the iPLEDGE Program. In order to help you fulfill the requirements of the program, iPLEDGE must obtain personal information from you. Protecting your privacy is very important to us. The complete iPLEDGE Privacy Statement can be found at the bottom of home page at <http://www.ipledgeprogram.com/> by choosing the "Privacy Statement" feature.
- **What happens if a patient loses his or her iPLEDGE ID card?**
- **Where do I find a list of local pharmacies that participate in the iPLEDGE Program?**
- **What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?**
- **At what date and time does my prescription window close?**
- **Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?**
- **How can I download iPLEDGE materials?**
- **Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?**
- **I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?**

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

 HOME

 COMPREHENSION QUESTIONS

 CONTRACEPTION INFORMATION

 PATIENT INFORMATION

 ABOUT ISOTRETINDIN

 ABOUT iPLEDGE

Change Primary Prescriber

Find a Participating Pharmacy

Update My Information

My Program Status

FAQs / How to's

Patient – FAQs/How To's

Welcome iPledge Patient [Logout](#)
Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

Frequently Asked Questions (FAQ)

- At what date and time does my prescription window close?

Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may pick up your prescription. Patients will be provided with a message that states the ending date and time to pick up their prescription. This message has been updated to give patients the exact date and time when their window will close. For example, the message will read:

"You may pick up your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to fill and pick up their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.
- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?

Users can download the iPLEDGE materials from the website using Acrobat. The link to this free Acrobat download is available on any page that has materials available for download. The website has been updated to include additional documents for download and self-printing.
- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

Privacy Statement | Safety Notice | Non-Compliance Action Policy | © 2005 iPLEDGE

Patient – iPLEDGE Terms of Use

iPLEDGE[™]
Committed to Pregnancy Prevention

Welcome iPledge Patient
[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY →

iPLEDGE Terms of Use

iPLEDGE 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.

[iPLEDGE Terms of Use](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE

Navigation Links:
HOME
COMPREHENSION QUESTIONS
CONTRACEPTION INFORMATION
PATIENT INFORMATION
ABOUT ISOTRETINOIN
ABOUT iPLEDGE
Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

Patient – Safety Notice



iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPledge Patient

[Logout](#)

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY 

 HOME

 COMPREHENSION
QUESTIONS

 CONTRACEPTION
INFORMATION

 PATIENT
INFORMATION

 ABOUT
ISOTRETINOIN

 ABOUT
iPLEDGE

[Change Primary Prescriber](#)

[Find a Participating Pharmacy](#)

[Update My Information](#)

[My Program Status](#)

[FAQs / How to's](#)

Safety Notice

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.

[Privacy Statement](#) [Safety Notice](#) [Non-Compliance Action Policy](#) © 2005 iPLEDGE