

Most Recent Modification:
NOVEMBER 2016



iPLEDGE[®]
Committed to Pregnancy Prevention

The iPLEDGE Program



Patient Introductory Brochure

The important information you need to know about isotretinoin and the iPLEDGE Program before starting treatment

Are you thinking about taking isotretinoin (eye-soh-tret-in-OH-in) for acne? Read this brochure to learn more about isotretinoin and the iPLEDGE Program.

WARNING

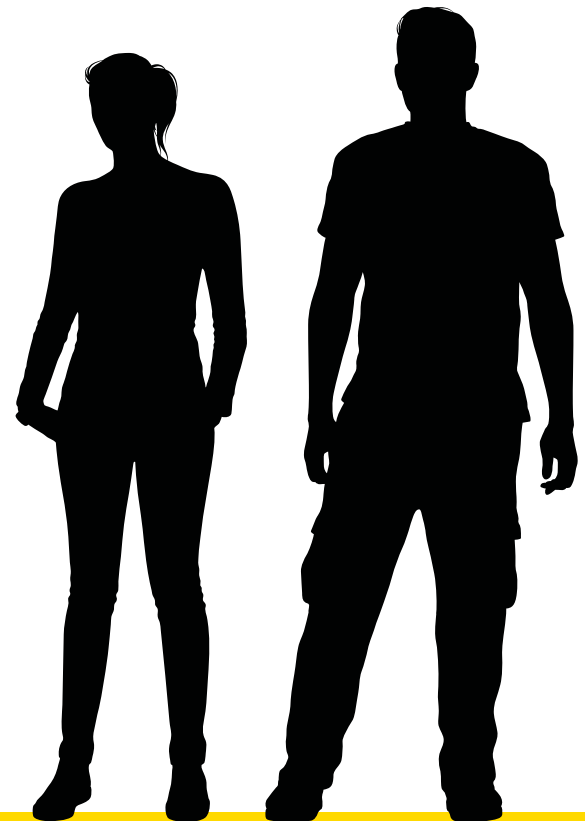
For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.



What Is Isotretinoin?

Isotretinoin (eye-soh-tret-in-OH-in) is a prescription medication that treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months. Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. You should also learn about the side effects and the precautions and warnings (see the enclosed sheet entitled **Safety Information About Isotretinoin**). Talk with your doctor about how bad your acne is and how isotretinoin can help your skin. Decide if isotretinoin is right for you. Your doctor will ask you to read and sign forms that say you understand the serious risks of isotretinoin. It is important for you to know how to take isotretinoin correctly and what to expect.



What Is The iPLEDGE[®] Program?

The iPLEDGE Program is a set of steps all patients, doctors/prescribers, and pharmacists must follow. The main goal is preventing pregnancy and birth defects, but both male patients and female patients must follow the iPLEDGE Program. To avoid serious risks to unborn babies, the Food and Drug Administration (FDA) has required a special Program called a Risk Evaluation and Mitigation Strategy (REMS) for isotretinoin. The iPLEDGE Program is a single, shared (includes multiple manufacturers) system with requirements for prescribers, pharmacies, and patients. The iPLEDGE Program also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE Program is to

- prevent pregnancies in females taking isotretinoin and to
- prevent pregnant females from taking isotretinoin

Only registered and activated prescribers can prescribe isotretinoin and only registered and activated pharmacies can dispense isotretinoin. In order to receive isotretinoin, all patients must be enrolled in the iPLEDGE Program and agree to follow the requirements.

All patients must:

- Sign the Patient Information/Informed Consent form(s)
- Be able to keep appointments
- Agree to follow the iPLEDGE Program steps



Safety Information About Isotretinoin

What Is The Most Important Information I Should Know About Isotretinoin?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE® Program.
- Isotretinoin may cause serious mental health problems.

1. Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.

Female patients must not get pregnant:

- For 1 month before starting isotretinoin
- While taking isotretinoin
- For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor.

Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. Serious mental health problems. Isotretinoin may cause:

- **Depression**
- **Psychosis** (seeing or hearing things that are not real)
- **Suicide**

Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.





Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See “**What is the most important information I should know about isotretinoin?**”) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the Program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See “What is the most important information I should know about isotretinoin?”)
- Do not take isotretinoin if you are allergic to anything in it.

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John’s Wort.** This herbal supplement may make birth control pills work less effectively.

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.



How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE[®] Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise.
Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule. Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do not take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate methods of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. **You must access the iPLEDGE Program system to answer questions about the Program requirements and to enter your 2 chosen methods of birth control.** To access the iPLEDGE Program system, go to www.ipledgeprogram.com or call **1-866-495-0654**.

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this free visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 methods of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See “**What is the most important information I should know about isotretinoin?**”)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See “**What should I tell my doctor before taking isotretinoin?**”)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

What Are The Possible Side Effects of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See “**What is the most important information I should know about isotretinoin?**”)
- **Isotretinoin may cause serious mental health problems.** (See “**What is the most important information I should know about isotretinoin?**”)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
 - Bad headache
 - Blurred vision
 - Dizziness
 - Nausea or vomiting
 - Seizures (convulsions)
 - Stroke





- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like “pink eye”), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach).

If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:

- Severe stomach, chest, or bowel pain
 - Trouble swallowing or painful swallowing
 - New or worsening heartburn
 - Diarrhea
 - Rectal bleeding
 - Yellowing of your skin or eyes
 - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
 - Back pain
 - Joint pain
 - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.

What Are The Possible Side Effects of Isotretinoin? (Cont.)

- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
 - **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
 - **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
 - **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children.**

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for healthcare professionals. You can also call iPLEDGE® Program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.



Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling **1-866-495-0654** or via **www.ipledgeprogram.com**.



iPLEDGE[®]

Committed to Pregnancy Prevention



Web site: www.ipledgeprogram.com

Phone system: 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.