

www.ipledgeprogram.com 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.

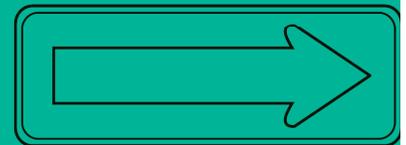
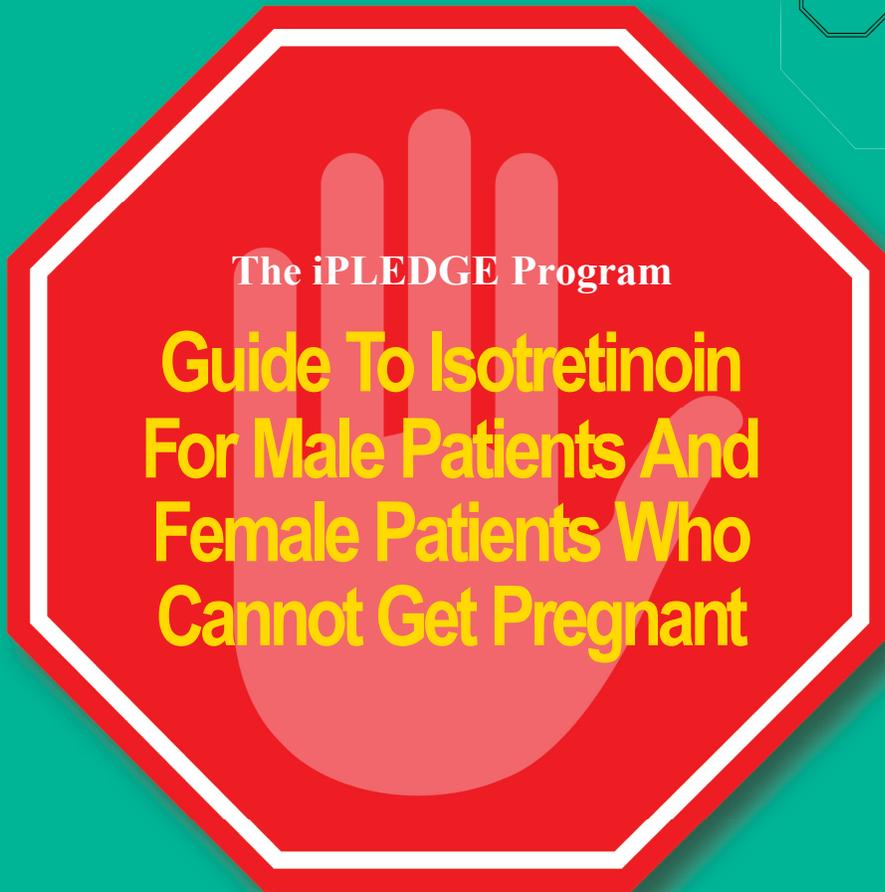
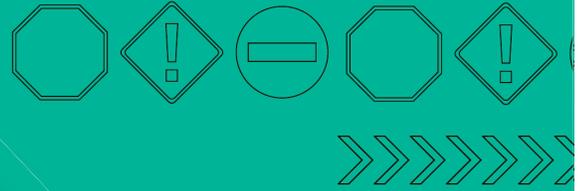
Fill and pick up your isotretinoin prescriptions *only* at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE program.

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iPLEDGETM
Committed to Pregnancy Prevention

Most Recent Modification: April 2012



The resource to help you prepare and plan treatments during the course of isotretinoin treatment

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iPLEDGETM
Committed to Pregnancy Prevention

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant

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ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) 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. The goal of the iPLEDGE program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.

Even if you are a male or a female patient who cannot get pregnant, the iPLEDGE program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin. You should also learn about the side effects and the precautions and warnings.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant* and make sure you understand the requirements of the iPLEDGE program. Then decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR MALE PATIENTS AND FEMALE PATIENTS WHO CANNOT GET PREGNANT

> Birth Defects

There is a very high chance that babies born to female patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a female patient takes isotretinoin for only a short time. It may also happen if a pregnant female receives a blood transfusion from someone taking isotretinoin.

Do male patients taking isotretinoin need to worry about birth defects?

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.

If you are worried about isotretinoin birth defects from sperm, you can use a male latex condom to help prevent pregnancy. Use a condom each and every time you have intercourse (sex) while you are taking isotretinoin and for 1 month after you stop taking it.

Can isotretinoin affect a male patient's ability to father healthy children?

Studies on isotretinoin did not show effects on sperm count, how sperm look, or how well they swim and move.

> Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant female gets blood from you. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

> Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 8 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant and your educational kit are resources for the information you need about isotretinoin and the iPLEDGE program. The iPLEDGE program also has a web site and an automated phone system.

- Web site: www.ipleddgeprogram.com
- Phone system: 1-866-495-0654

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID cardcards, and other program materials. You use these to log in to the system. (see page 5)

After you have been registered in iPLEDGE by your doctor, you will receive your iPLEDGE password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant explains the information about the iPLEDGE program before, during, and after your isotretinoin treatment. Here is a general overview:

- Learn about the iPLEDGE program and the isotretinoin side effects and risks in pregnancy.
- Plan for treatment and appointments.
- Sign the Patient Information/Informed Consent (for all patients) form.
- Keep monthly appointments.
- Do not donate blood during your treatment or 1 month after your last dose.
- Do not share isotretinoin.

You can use the checklist on the next page as a quick reminder of the program information during your isotretinoin treatment.

THE IPLEDGE PROGRAM CHECKLIST

All patients have a specific period of time in which they can fill and pick up their prescription. This is called the “prescription window” and its start and end dates depend on the type of patient.

Male patients and female patients who cannot get pregnant

The prescription window is 30 days and starts on the date the prescriber enters as the date of your office visit. This date is counted as DAY 1.

To determine the end date of your 30-day prescription window, you should add 29 days to the date of your office visit.

After 11:59 p.m. Eastern Time on the last day of the 30-day prescription window, you can no longer fill and pick up your prescription, and must start the process over to get a new 30-day prescription window.

PLANNING

- Plan** your course of treatment (about 4 to 5 months).
- Talk** with your doctor about isotretinoin and the iPLEDGE program.
- Sign** the Patient Information/Informed Consent (for all patients) form.
- Get** your patient ID card containing your patient ID number from your doctor. (*see page 5*)
- Receive** your password in the mail.

**Before
Treatment**

PRESCRIPTION

- Get** your prescription for a maximum of up to a 30-day supply.
- Fill and Pick up** your prescription within the 30-day prescription window counting your office visit as DAY 1. (*see page 6*)

**During
Treatment**

- Keep** your appointments every month to get your prescription.
- Fill and Pick up** your prescription within the 30-day prescription window counting the office visit as DAY 1. If you do not fill and pick up your prescription within the 30-day prescription window, you will be required to start the process over again by visiting your doctor.
- Do not donate blood.**

**After
Treatment**

Do not donate blood for 1 month after your last dose.




THE iPLEDGE PROGRAM CHECKLIST INFORMATION

> Plan Your Course Of Treatment

The most isotretinoin you can get at any one time is a maximum of up to a 30-day supply. You will need to see your doctor each month to get a new prescription.

> Get Your Patient ID Number And ID Cards

Your doctor will give you your patient ID cards, containing your patient ID number, when you start the iPLEDGE program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. Write your number down as soon as you receive it, and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled and dispensed at the pharmacy
- When you log in to the iPLEDGE program system, either the web site, www.ipledgeprogram.com, or phone line, **1-866-495-0654**

> About The iPLEDGE System

The first time you login to iPLEDGE (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using iPLEDGE.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can fill and pick up your prescription
- Change to a new doctor
- Get information about isotretinoin
- View information about your current status
- View FAQ's (Frequently Asked Questions)

If you lose your Patient ID Cards, and cannot remember your Patient ID number, contact your doctor.

> Informed Consents

You must sign the Patient Information/Informed Consent (for all patients) form to be in the iPLEDGE program.

Signing the informed consent means you understand that there are risks associated with taking isotretinoin.

> Fill And Pick Up Your Prescription

Fill and pick up your isotretinoin prescriptions only at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE program.

The web site, www.ipledgeprogram.com, has a list of registered pharmacies. Log in and choose “Find a Participating Pharmacy” in the left navigation.

Your pharmacist will contact the iPLEDGE system before filling your prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only get isotretinoin if:

- Your doctor entered your patient information in the iPLEDGE system
- You can fill and pick up the prescription within the 30-day prescription window, counting the office visit as DAY 1. Please see your doctor if you did not pick up your prescription within the 30-day prescription window.

The system will automatically compute the “Do Not Dispense To Patient After” date for your pharmacist.

To figure out the last date you can fill and pick up your prescription, add 29 days to the date of your office visit. For example:

| Day 1 Day of the office visit | Day 2 – Day 29 | Day 30 – Last day to fill and pick up prescription |
|--|--|---|
| (Friday, March 1) | (Saturday, March 2 thru Friday, March 29) | (Saturday, March 30) |

The 30-day prescription window expires at 11:59 p.m. Eastern Time on Day 30 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 30-day prescription window expires before you fill and pick up your prescription, you can start a new 30-day prescription window right away, but you must repeat the program requirements to get another prescription.

Additional information about your status, can be found by selecting “My Program Status” on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.





A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

> After Your Last Dose

It is very important that:

- You do NOT give blood for 1 month after your last dose
- You do not share any leftover isotretinoin with anyone

> Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE web site, www.ipledgeprogram.com, or phone line, **1-866-495-0654**.

You need your patient ID number and password to log in to the system.

To change your doctor on the iPLEDGE web site:

1. Log in
2. Choose “Change Primary Prescriber” from the menu
3. You need to enter the following information about your new doctor:
 - First and last name
 - City
 - Phone number

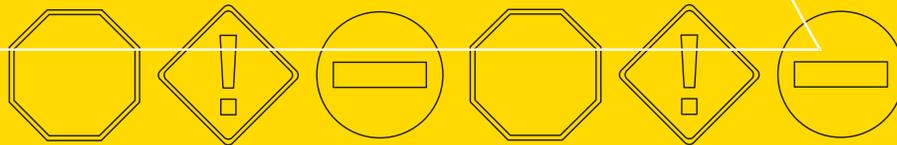
To change your doctor on the automated phone line:

1. Log in
2. Select the option for “More Choices”
3. Select “Change Your Prescriber”
4. Follow the prompts to enter the new information

The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE system before being able to give you a prescription.

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 forms 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 system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE 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 forms 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.
- **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 health care professionals. You can also call iPLEDGE program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.



For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE program, ask your doctor, visit the iPLEDGE program web site at www.ipledgeprogram.com, or call **1 866-495 0654**.

For private birth control information, you can reach the iPLEDGE automated phone line 24 hours a day, 7 days a week at **1 866-495-0654**. You can learn about different subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

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.