



Patient Information Sheet

Isotretinoin (marketed as Accutane)

This is a summary of the most important information about isotretinoin. For details, talk to your healthcare professional.

FDA ALERT [11/2005]: Start Dates Have Been Changed for the iPLEDGE Program.

FDA approved a strengthened risk management plan for Accutane and generic isotretinoin on August 12, 2005, to make sure females do not become pregnant while taking this medicine. Isotretinoin causes birth defects. This new plan is called iPLEDGE. For details of iPLEDGE go to <http://www.fda.gov/cder/drug/infopage/accutane/default.htm>. The iPLEDGE program was originally scheduled to begin on November 1, 2005. To allow more time for registration and activation, the implementation dates of the iPLEDGE program have been revised. The date by which wholesalers and pharmacies must be registered/activated in iPLEDGE has been changed from November 1, 2005 to December 30, 2005. The starting date to begin patient registration and qualification in iPLEDGE has been changed from November 1, 2005 to December 30, 2005. By March 1, 2006, only prescribers registered and activated in iPLEDGE will be able to prescribe isotretinoin and only patients registered and qualified in iPLEDGE will be dispensed isotretinoin.

[07/2005]: **SUICIDAL THOUGHTS OR ACTIONS:** In addition to the strengthened risk management program for pregnancy, FDA continues to assess reports of suicide or suicide attempts associated with the use of isotretinoin. All patients treated with isotretinoin should be observed closely for symptoms of depression or suicidal thoughts, such as sad mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating, or for mood disturbance, psychosis, or aggression. Patients should stop isotretinoin and they or their caregiver should contact their healthcare professional right away if the patient has any of the previously mentioned symptoms. Discontinuation of treatment may be insufficient and further evaluation may be necessary. [Action taken 08/12/2005: Labeling revision]

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available.

What Is Isotretinoin?

Isotretinoin is used to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments,

including antibiotics. Isotretinoin is only for patients who understand and agree to carry out all the instructions in the iPLEDGE program, because isotretinoin can cause serious side effects.

Who Should Not Take Isotretinoin?

Isotretinoin should NOT be used by pregnant women.

Do not take isotretinoin if you are:

- Pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment
- Breast-feeding
- Allergic to anything in it. Isotretinoin contains parabens, which are used as preservatives in the gelatin capsule.

What Are The Risks?

Birth defects (deformed babies), loss of baby before birth (miscarriage), death of 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.

- **Serious mental health problems:** Isotretinoin may cause:
 - Depression
 - Psychosis (seeing or hearing things that are not real)
 - Suicidal thoughts or actions
 - Aggressive and violent behavior

Stop taking isotretinoin and call your doctor right away if you:

- 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
- Have a change in your appetite or body weight
- Withdraw from your family or friends
- Feel like you have no energy



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@cder.fda.gov



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- Have feelings of worthlessness or wrong 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
- **Serious brain problems:** Isotretinoin may increase the pressure in your brain, possibly leading to permanent loss of eyesight, or in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any signs of increased brain pressure such as bad headaches, blurred vision, dizziness, nausea or vomiting, seizures (convulsions) or stroke.
 - **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). 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, or dark urine.
 - **Bone and muscle problems:** Tell your doctor if you plan any vigorous physical activity during treatment with isotretinoin. Tell your doctor if you get muscle weakness, back pain, joint pain, or a broken bone.
 - **Hearing problems:** Stop taking isotretinoin and call your doctor if you're hearing gets worse or if you have ringing in the ears.
 - **Vision problems:** Isotretinoin may affect your ability to see in the dark. 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.
 - **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:** 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.

What Should I Do Before Taking Isotretinoin?

- Tell your healthcare professional if you or someone in your family has had any kind of mental problems, asthma, liver disease, diabetes, heart disease, osteoporosis (bone loss), weak bones, an eating problem called anorexia nervosa (where people eat too little), or any food or medicine allergies.
- By March 1, 2006, all patients must be registered and activated by their doctors in iPLEDGE to get isotretinoin. You must sign the Patient Information/Informed Consent form.
- You must agree to or follow all the instructions in the iPLEDGE program.
- By March 1, 2006, only prescriptions from iPLEDGE doctors will be filled by iPLEDGE pharmacies.
- If you have sex anytime without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

Females who can become 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 stopping isotretinoin. You must also call and enter your 2 types of birth control each month into the iPLEDGE system by telephone or the internet.
- Have negative results from 2 pregnancy tests before receiving the initial isotretinoin prescription.
- Have a negative pregnancy test before each refill.
- Sign an additional Patient Information/Consent form that contains warnings about the risk of potential birth defects if the fetus is exposed to isotretinoin.





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Are There Any Interactions With Drugs Or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Isotretinoin and other medicines may affect each other sometimes causing serious side effects. Especially tell your healthcare professional if you take:

- Progestin-only containing birth control pills (“minipills”)
- Vitamin A supplements
- Tetracycline medicines
- Dilantin (phenytoin)
- Corticosteroid medicines
- St. John’s Wort

Is There Anything Else I Need to Know?

- 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 drive at night until you know if isotretinoin has affected your vision. 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.

- Avoid sunlight and ultraviolet lights as much as possible. Tanning machines use ultraviolet lights.
- Do not share isotretinoin with other people. It can cause serious birth defects and other serious health problems.
- You will only be able to get up to a 30-day supply of isotretinoin at one time. Refills will require you to get a new prescription from your doctor. The prescription must be filled within 7 days of your office visit.
- You should receive an Isotretinoin Medication Guide each time you receive isotretinoin. This is required by law.

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