

Isotretinoin and the iPLEDGE Program

Names

The generic drug name is isotretinoin (eye soe tret' i noyn). There are a number of brand name medications for this drug including Absorica®, Claravis®, and Zenatane®. Sometimes it is referred to as Accutane, a brand name that is no longer available in the U.S. There may be other names for this medication.

Why Am I Taking this Drug and How Does it Work?

This drug is used to treat certain types of severe acne that has not been helped by other treatments, such as antibiotics. Sometimes, it is used to treat other skin conditions or some types of cancer. It is in a class of medications called retinoids, and it's related to vitamin A. It works by slowing the production of certain substances that can cause acne or other skin problems.

How Do I Take this Medication?

- This medicine comes as capsules. You take them by mouth.
- Typically, it is taken twice a day **with meals**. Your doctor may give you different instructions – if they do, follow your doctor's instructions. Do not use more medicine or use it more often than your doctor tells you to.
- Ask your doctor or pharmacist to explain any part you do not understand.
- If you miss a dose, skip it, and continue your regular dosing schedule. **Do not take a double dose to make up for a missed one.**
- It may take several weeks or longer for you to feel the full benefit of isotretinoin. When you first start using this medicine, your acne may get worse. This is normal and does not mean that the medication is not working. Your acne may improve even after you finish your treatment.

What Should I Tell My Doctor Before I Begin?

Tell your doctor if you:

- are allergic to isotretinoin, vitamin A, or if you have any other allergies
- are taking seizure medicines (phenytoin/Dilantin); medications for mental illness; oral steroids (dexamethasone, prednisone); tetracycline antibiotics; or vitamin. Your doctor may change your dose or monitor you.
- or anyone in your family has ever had depression; mental illness; thought about or attempted suicide; or drink large amounts of alcohol
- or anyone in your family has or has ever had diabetes, asthma, osteoporosis or osteomalacia (conditions where bones become weak and are more likely to fracture), high cholesterol or triglycerides; anorexia nervosa eating disorder; or heart or liver disease

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about all prescription or over-the-counter medications, vitamins, herbal or diet supplements that you are taking.

Please let us know ahead of time if you have had any allergic reactions or side effects to any medicines you have received in the past.

What Are Some Possible Side Effects?

- Skin/Hair: Dry skin, eyes, mouth, or nose; changes in skin color; peeling skin on the palms of the hands and soles of the feet; changes in the nails; red, cracked lips; slower healing; hair loss or unwanted hair growth
- Bleeding or swollen gums, nosebleeds
- Sweating, flushing
- Voice changes
- Cold symptoms, tiredness
- Birth defects, loss of pregnancy, and fetal or infant death - see iPLEDGE on last page

How Can I Manage These Side Effects?

- Drink 2-3 quarts of fluids a day, especially water, unless your doctor has restricted your fluids.
- **Skin care:** You may be more sensitive to sunlight (photosensitivity). Take extra care to avoid sun exposure. Use a sunblock with SPF 30 or higher that protects against both UVA and UVB rays when outdoors, even if it is just for a short time. Wear sunglasses and protective clothes (brimmed hat, long sleeves, etc.) when in the sun. Do not use tanning beds. If you develop a rash, keep the area clean and dry and check with your doctor before using any creams or ointments on the area.
- During treatment, and for 6 months afterwards, do not wax (to remove hair), laser skin treatments, or dermabrasion. Isotretinoin increases the risk of scarring from these treatments. Ask your doctor when you can safely undergo these treatments.
- **Nosebleed prevention:** Keep nostrils moist by using a humidifier or not increasing the temperature too high at home.
- **Sweating, flushing:** Wear light cotton or linen clothing (avoid wool and synthetics), use cotton bed sheets, layer your clothes, stay in a cool environment, keep ice water nearby, put cool clothes on your head, and try using a personal size fan that sprays a mist.
- Ask your doctor before taking any medicines or products for any side effect.

Continued on next page

- **Mouth care:** To help prevent mouth sores, rinse your mouth with a mixture of ½ teaspoon of baking soda in 8 ounces of water after every meal and at bedtime. Brush your teeth and gums often with a soft toothbrush. Do not use alcohol, mouthwashes that contain alcohol, or tobacco products.
- Do not breast-feed while you are taking isotretinoin and for 1 month after treatment ends.
- **Do not get pregnant or father a child while in treatment.** See important iPLEDGE information/warnings on last page.

When Should I Call the Doctor?

Call 911 or go to the nearest hospital emergency department if you have life-threatening symptoms such as signs of severe allergic reaction: Swelling or tingling in your face, tongue, mouth, or throat; chest tightness; wheezing; trouble breathing or swallowing; dizziness, shortness of breath; heart palpitations; or hives.

Please let us know if you go to the emergency room or are admitted to the hospital.

Call your doctor immediately if you have:

- **fever of 100.4°F (38°C) or higher**, chills, cough, sore throat, pain or burning upon urination; redness or tenderness along a vein, at an IV site, or at any other wound or skin irritation (may be signs of infection)
- sudden and severe stomach pain, chills, constipation, nausea, vomiting, fever, or lightheadedness (may be signs of pancreatitis)

Call your doctor as soon as possible (within 1 day) if you have:

- hearing problems starting within a few weeks
- painful sores/ulcers on skin, lips, or mouth; blisters; rash; or peeling skin
- any side effect that prevents you from eating or drinking
- unusual bruising or bleeding: Bleeding lasts more than 10-15 minutes or that causes dizziness; black or bloody stools; vomit that is bloody or that looks like coffee grounds; blood in your urine or phlegm /mucus, unusually heavy menstrual bleeding, spontaneous bleeding from your gums or nose, or superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots (petechiae)

iPLEDGE Program

Since isotretinoin carries a high risk of pregnancy loss and birth defects, a program called iPLEDGE has been set up to prevent these risks. **The iPLEDGE program makes sure that pregnant women do not take isotretinoin and that women do not become pregnant while taking isotretinoin.** All patients, even men and women who cannot get pregnant must:

- sign an informed consent sheet stating that you understand the risks and your responsibilities before you can receive isotretinoin
- register with iPLEDGE
- get their prescription from a doctor who is registered with iPLEDGE
- fill the prescription at a pharmacy that is registered with iPLEDGE (Do not buy it over the internet.)

HOW IPLEDGE Works

- After you register on the website, you will receive an identification number when you start your treatment. You'll need your ID number to get your prescription. You may also receive the manufacturer's patient information sheet each time the prescription is filled.
- Keep the ID number in a safe place where it will not get lost.
- **You must see your doctor every month during treatment** to talk about your condition and any side effects.
- Do not donate blood while you are taking isotretinoin and for 1 month after your treatment.
- Do not share isotretinoin with anyone else, even someone who has the same symptoms that you have.

Instructions for female patients who can become pregnant

NOTE: Only women who have passed menopause (not menstruated for 12 months in a row) or had a hysterectomy are excused from these requirements. Women who have had a tubal ligation (tubes tied) must meet these requirements.

- Before starting this medication: You must have 2 negative pregnancy tests. Your doctor will tell you when and where to have these tests. During treatment, you must be tested for pregnancy in a lab each month until 30 days after you take your last dose.
- **You must commit to using 2 acceptable forms of birth control to prevent pregnancy for 1 month before you begin to take isotretinoin, during your treatment and for 1 month after your treatment.**
- Your doctor will tell you which forms of birth control are acceptable. You must use these 2 forms of birth control at all times unless you can promise that you will not have any sexual contact with a male for 1 month before your treatment, during your treatment, and for 1 month after your treatment.
- **Remember: Any form of birth control can fail.** Discuss your birth control options with your doctor and ask if any of the information is confusing.

Continued on next page

- Tell your doctor if you do not think that you will be able to use 2 forms of birth control at all times.
- If you plan to use oral contraceptives (birth control pills), tell your doctor what pill you are using. **Do not use 'minipill' oral contraceptives such as Ovrette**, isotretinoin can interfere with their effectiveness.
- If you going to use a form of birth control that contains hormones (birth control pills, patches, implants, injections, rings, or intrauterine devices/IUDs), make sure your doctor knows about ALL the medications and products – including vitamins and supplements - you are taking. Many medications interfere with the action of hormonal contraceptives. Do not take St. John's wort with any hormonal contraceptive.
- You must contact the iPLEDGE system by phone or online every month to confirm the 2 forms of birth control you are using and to answer 2 questions about the iPLEDGE program. 1) If you have visited your doctor to talk about how you are feeling and 2) if you have had a negative pregnancy test
- If you think you are pregnant, you miss a menstrual period, or you have sex without using 2 forms of birth control: stop taking isotretinoin and **call your doctor right away**.
- If you become pregnant during your treatment or within 30 days after your treatment, your doctor will contact the iPLEDGE program, the manufacturer of isotretinoin, and the Food and Drug Administration (FDA). You will also talk with a doctor who specializes in problems during pregnancy who can help you make choices that are best for you and your baby.

For male patients

A very small amount of isotretinoin may be in your semen when you take this medication. It is not known if this may be harmful to a fetus if your partner gets pregnant. Tell your doctor right away if your partner is pregnant or becomes pregnant during your treatment with isotretinoin.

Picking Up your medication

- If you are a woman who can become pregnant: You must have a pregnancy test in an approved lab before starting this medication and have your prescription filled and picked up within 7 days of your pregnancy test. (You will need to take a pregnancy test every month.)
- If you are a man or if you are a woman who cannot become pregnant: Fill and pick up your prescription within 30 days of your doctor visit.
- Your pharmacist cannot dispense your medication if you come to pick it up after the allowed time period has passed.