

ISOTRETINOIN CAPSULES

INDICATIONS AND USAGE

Isotretinoin capsules are retinoids indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, isotretinoin capsules are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. (1)

Limitations of Use:
If a second course of isotretinoin therapy is needed, it is not recommended before a two-week waiting period because the patient's acne may continue to improve following a 15 to 20-week course of treatment. (2)

DOSE AND ADMINISTRATION

Recommended dosage for isotretinoin capsules is 0.5 to 1 mg/kg/day given in two divided doses without regard to meals for 15 to 20 weeks (2).

Adult patients with very severe disease (scarring, trunk involvement) may increase dosage to 1 mg/kg/day in two isotretinoin capsules in divided doses.

Isotretinoin capsules are available only through a restricted program called the iPLEDGE REMS. (5, 7)

CONTRAINDICATIONS

Isotretinoin capsules are contraindicated in pregnancy. (See **Warnings and Precautions (5.1)** and **Use in Specific Populations (8.1, 8.3)**)

WARNINGS AND PRECAUTIONS

5.1 Embryo-Fetal Toxicity — Isotretinoin capsules are contraindicated in pregnancy. (See **Warnings and Precautions (5.1)** and **Use in Specific Populations (8.1, 8.3)**)

5.2 Musculoskeletal Abnormalities — Arthralgias, back pain, decreases in bone mineral density and premature epiphyseal closure (5, 12)

5.3 Ocular Abnormalities — e.g., corneal opacities, decreased night vision; if visual symptoms occur, discontinue and refer patient to ophthalmologist (5, 6)

5.4 Hearing Impairment — Discontinue and refer to specialist care (5, 9)

5.5 Laboratory Testing — Monitor liver function tests prior to and during therapy (5.10, 5.15)

5.6 Serious Skin Reactions — Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and other serious skin reactions (5, 6)

5.7 Pancreatitis — If occurs, discontinue treatment (5, 7)

5.8 Lipid Abnormalities (hypertriglyceridemia, low HDL, and elevation of cholesterol). Monitor lipid levels at regular intervals; stop if hypertriglyceridemia is severe (See **Warnings and Precautions (5.12)**).

5.9 Hearing Impairment — Discontinue and refer to specialist care (5, 9)

5.10 Laboratory Testing — Monitor liver function tests prior to and during therapy (5.10, 5.15)

5.11 Inflammatory Bowel Disease — Discontinue for abdominal pain, rectal bleeding, or severe diarrhea (5.11)

5.12 Musculoskeletal Abnormalities — Arthralgias, back pain, decreases in bone mineral density and premature epiphyseal closure (5, 12)

5.13 Ocular Abnormalities — e.g., corneal opacities, decreased night vision; if visual symptoms occur, discontinue and refer patient to ophthalmologist (5, 6)

5.14 Hearing Impairment — Discontinue and refer to specialist care (5, 9)

5.15 Laboratory Testing — Monitor liver function tests prior to and during therapy (5.10, 5.15)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, dryness of mouth, conjunctivitis, dermatitis, increased creatine kinase, hematuria, musculoskeletal discomfort, upper respiratory tract infection, reduced visual acuity (6)

DRUG INTERACTIONS

7.1 Vitamin A — may cause additive adverse reactions (7, 1)

7.2 Tetracyclines — avoid concomitant use (7, 2)

7.3 Norethindrone and ethinyl estradiol — avoid concomitant use (7, 2)

USE IN SPECIFIC POPULATIONS

8.1 Pregnancy — Breastfeeding not recommended (8.2)

8.2 Lactation — Breastfeeding not recommended (8.2)

8.3 Female and Male of Reproductive Potential — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.4 Pediatric Use — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.5 Geriatric Use — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.6 Serious Skin Reactions — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.7 Pancreatitis — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.8 Lipid Abnormalities — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

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8.11 Inflammatory Bowel Disease — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

8.12 Musculoskeletal Abnormalities — See Section 17 for PATIENT COUNSELING INFORMATION and Medication Guide

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INDICATIONS AND USAGE

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Limitations of Use:
If a second course of isotretinoin therapy is needed, it is not recommended before a two-week waiting period because the patient's acne may continue

Because isotretinoin capsules can cause birth defects, isotretinoin capsules are only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.

- **Serious mental health problems, including:**
 - **depression**
 - **psychosis** (seeing or hearing things that are not real)
 - **suicide**. Some patients taking isotretinoin capsules have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. Some people have ended their own lives.

Stop taking isotretinoin capsules and call your healthcare provider 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

Your healthcare provider may tell you to see a mental healthcare professional if you had any of these symptoms.

What are isotretinoin capsules?

Isotretinoin capsules are prescription medicines used in patients 12 years of age and older, who are not pregnant, for the treatment of severe acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin capsules can cause serious side effects (see “**What is the most important information I should know about isotretinoin capsules?**”).

Isotretinoin capsules can only be:

- prescribed by healthcare providers 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.

It is not known if isotretinoin capsules are safe and effective in children less than 12 years of age.

Do not take isotretinoin capsules if you:

- **are pregnant, plan to become pregnant, or become pregnant during isotretinoin capsules treatment.** Isotretinoin capsules cause severe birth defects. See “**What is the most important information I should know about isotretinoin capsules?**”
- **are allergic to isotretinoin, vitamin A, or any of the ingredients in isotretinoin capsules.** See the end of this Medication Guide for a complete list of ingredients in isotretinoin capsules.

Before taking isotretinoin capsules, tell your healthcare provider if you or a family member has any of the following health conditions:

- mental health problems
- asthma
- liver problems
- diabetes
- heart disease
- increase blood fat levels (cholesterol and triglycerides)
- bone loss (osteoporosis), weak bones or any other bone problems
- an eating problem called anorexia nervosa (where people eat too little)
- food or medicine allergies, including aspirin or tartrazine

Tell your healthcare provider if you are pregnant or breastfeeding. Do not breastfeed during treatment or for at least 8 days after the last dose of isotretinoin capsules.

Tell your healthcare provider about all of the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements, including St. John’s Wort. Isotretinoin capsules and certain other medicines can affect each other, sometimes causing serious side effects.

Do not take the following medicines during treatment with isotretinoin capsules:

- vitamin A supplements
- tetracycline antibiotics

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

How should I take isotretinoin capsules?

You must take isotretinoin capsules exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing

- isotretinoin capsules, your healthcare provider will:
- explain the iPLEDGE Program to you
 - have you sign the Patient Information/Informed Consent form (for all patients). Patients who can get pregnant must also sign another consent form.
 - give you a pregnancy test to make sure you are not pregnant before you start isotretinoin capsules. You will receive 2 pregnancy tests at least 19 days apart.

You will not be prescribed isotretinoin capsules 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 capsules at a time. This is to make sure you are following the isotretinoin capsules iPLEDGE Program.
- The amount of isotretinoin capsules you take has been specially chosen for you. It is based on your body weight and may change during treatment.
- Take isotretinoin capsules 2 times a day with or without meals, unless your healthcare provider tells you otherwise. **Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Isotretinoin capsules can hurt the tube that connects your mouth to your stomach (esophagus) if not swallowed whole.

- Your healthcare provider will tell you how long you will receive treatment with isotretinoin capsules. Your acne may continue to improve after treatment.

- If you miss a dose, just skip that dose. **Do not** take two doses at the same time.

- If you take too much isotretinoin capsules, call your healthcare provider or poison control center right away.

- Your acne may get worse when you first start taking isotretinoin capsules. This should last only a short while. Talk with your healthcare provider if this is a concern for you.

- You must return to your healthcare provider as directed to make sure you don’t have signs of serious side effects. Your healthcare provider may do blood tests to check for serious side effects from isotretinoin capsules and may stop treatment if you get certain side effects.

- Patients who can get pregnant will get a pregnancy test each month, after you finish your course of treatment, and 1 month after you stop treatment with isotretinoin capsules.

- Patients who can get pregnant must use two separate forms of birth control at the same time for at least 1 month before, during treatment, and for 1 month after treatment with isotretinoin capsules. **You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your two chosen forms of birth control.** To access the iPLEDGE Program system, go to www.ipledgeprogram.com or call 1-866-495-0654.

Talk about birth control options with your healthcare provider or go for a free visit to talk about birth control with another healthcare provider or family planning expert. Your healthcare provider can arrange this **free** visit, which will be paid for by the company that makes isotretinoin capsules.

If you have sex at any time without using two forms of birth control 1 month before, during, or 1 month after treatment, get pregnant, or miss your expected period, stop taking isotretinoin capsules and call your healthcare provider right away.

What should I avoid while taking isotretinoin capsules?

- **Do not give blood** during treatment with isotretinoin capsules and for one month after stopping isotretinoin capsules. If someone who is pregnant gets your donated blood, their baby may be exposed to isotretinoin and may be born with birth defects.

- **Do not take other medicines or herbal products** with isotretinoin capsules unless you talk to

your healthcare provider. See “**Before taking isotretinoin capsules**”.

- **Do not drive at night until you know if isotretinoin capsules have affected your vision.** Isotretinoin capsules may decrease your ability to see in the dark.

- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, during treatment with isotretinoin capsules and for at least 6 months after you stop.** Isotretinoin capsules can increase your chance of scarring from these procedures. Check with your healthcare provider for advice about when you can have cosmetic procedures.

- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin capsules may make your skin more sensitive to light.

- **Do not share isotretinoin capsules with other people.** Isotretinoin capsules can cause birth defects and other serious health problems.

What are the possible side effects of isotretinoin capsules?

Isotretinoin capsules can cause serious side effects, including:

- See “**What is the most important information I should know about isotretinoin capsules?**”

- **increased pressure in the brain (intracranial hypertension).** Isotretinoin capsules can increase the pressure in your brain. This can lead to permanent loss of eyesight, and in rare cases, death. Stop taking isotretinoin capsules and call your healthcare provider right away if you get any of these signs of increased brain pressure:

- bad headache
- blurred vision
- dizziness
- nausea or vomiting
- seizures (convulsions)
- stroke

- **serious skin problems.** Skin rash can occur in patients taking isotretinoin capsules. Sometimes rash can be serious and may lead to death. Stop using isotretinoin capsules and call your healthcare provider right away if you get:

- conjunctivitis (red or inflamed eyes, like “pink eye”)
- rash with a fever
- blisters on legs, arms or face
- sores in your mouth, throat, nose or eyes
- peeling of your skin

- **inflammation of your pancreas (pancreatitis)** can happen in patients who take isotretinoin capsules and can lead to death. Call your healthcare provider right away if you have any of the following symptoms of pancreatitis:

- severe upper stomach (abdomen) pain
- swelling of your stomach
- nausea and vomiting
- fever

- **increased blood fat (lipid) levels.** Isotretinoin capsules can raise blood fat levels (cholesterol and triglycerides). Your healthcare provider will do blood tests to check your lipids before and during treatment. These problems usually go away when isotretinoin capsules treatment is finished.

- **hearing problems.** Stop using isotretinoin capsules and call your healthcare provider if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.

- **liver problems, including hepatitis.** Your healthcare provider will do tests to check your liver before and during treatment with isotretinoin capsules. Call your healthcare provider if you get:

- yellowing of your skin or the whites of your eyes
- pain on the right side of your stomach area (abdomen)
- dark urine
- bleeding or bruising more easily than normal

- **inflammation of your digestive tract (inflammatory bowel disease).** Stop taking isotretinoin capsules and call your healthcare provider if you get:

- severe stomach, chest or bowel pain
- nausea or vomiting
- trouble swallowing or painful swallowing
- new or worsening heartburn
- diarrhea
- rectal bleeding

- **bone and muscle problems.** Bone problems include bone pain, softening or thinning (which may lead to fractures). Tell your healthcare

provider if you plan hard physical activity during treatment with isotretinoin capsules. Tell your healthcare provider if you get:

- back pain
- joint pain or muscle pain
- broken bone. Tell all healthcare providers that you take isotretinoin capsules if you break a bone.

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

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

- **vision problems.** Stop taking isotretinoin capsules and call your healthcare provider right away if you have any vision changes. isotretinoin capsules may affect your ability to see in the dark. This usually goes away after you stop taking isotretinoin capsules, but it may be permanent. Some patients get dry eyes during treatment. If you wear contact lenses, you may have trouble wearing them during and after you stop treatment with isotretinoin capsules.

- **serious allergic reactions.** Stop taking isotretinoin capsules and get emergency medical help right away if you get hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin capsules and call your healthcare provider if you get a fever, rash, or red patches or bruises on your legs.

- **blood sugar problems, including diabetes.** Tell your healthcare provider if you are very thirsty or urinate more than usual.

The most common side effects of isotretinoin capsules include:

- dry lips
- dry skin
- back pain
- dry eyes
- joint pain
- nose bleeds
- headache
- upper respiratory tract infection (common cold)
- chapped lips or swelling of the lips
- skin reactions
- muscle problems
- eye problems, including decreased vision

These are not all of the possible side effects of isotretinoin capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Upsher-Smith Laboratories, LLC at 1-855-899-9180.

How should I store isotretinoin capsules?

- Store isotretinoin capsules at room temperature, 68°F to 77°F (20°C to 25°C). Protect from light.

Keep isotretinoin capsules and all medicines out of the reach of children.

General Information about the safe and effective use of isotretinoin capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use isotretinoin capsules for a condition for which it was not prescribed. Do not give isotretinoin capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about isotretinoin capsules that is written for health professionals. You can also call iPLEDGE Program at 1-866-495-0654 or visit www.ipledgeprogram.com.

What are the ingredients in isotretinoin capsules?
Active ingredient: isotretinoin

Inactive ingredients: butylated hydroxyanisole, disodium edetate, hydrogenated vegetable oil Type I, hydrogenated vegetable oil Type II, soybean oil, vitamin E and yellow wax. The gelatin capsules contain the following: glycerin, iron oxide (red and yellow), ferrosulfate, sorbitol and titanium dioxide.

Manufactured for
UPSHER-SMITH LABORATORIES, LLC
Maple Grove, MN 55369

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