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2. Isotretinoin

Isotretinoin

Generic name: isotretinoin (oral) [*EYE-so-TRET-i-noyn*]**Brand names:** [Absorica](#), [Absorica LD](#), [Accutane](#), [Amnesteem](#), [Claravis](#), ... [show all 12 brands](#)**Dosage form:** oral capsule (10 mg; 20 mg; 25 mg; 30 mg; 35 mg; 40 mg; micronized 16 mg; micronized 24 mg; micronized 32 mg; micronized 8 mg)**Drug classes:** [Miscellaneous antineoplastics](#), [Miscellaneous uncategorized agents](#)[Medically reviewed](#) by Drugs.com on Jan 21, 2025. Written by [Cerner Multum](#).[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is isotretinoin?

Isotretinoin is a form of vitamin A that is used to treat severe nodular acne that has not responded to other treatments, including antibiotics.

Isotretinoin is available only from a certified pharmacy under a special program called iPLEDGE.

Isotretinoin may also be used for purposes not listed in this medication guide.

Isotretinoin side effects

Get emergency medical help if you have **signs of an allergic reaction** (hives, difficult breathing, swelling in your face or throat) or a **severe skin reaction** (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Isotretinoin may cause serious side effects. Stop using isotretinoin and call your doctor at once if you have:

- problems with your vision or hearing;
- muscle or joint pain, bone pain, back pain;
- increased thirst, increased urination;
- hallucinations, (see or hearing things that are not real);
- **symptoms of depression**--unusual mood changes, crying spells, feelings of low self-worth, loss of interest in things you once enjoyed, new sleep problems, thoughts about hurting yourself;
- **signs of liver or pancreas problems**--loss of appetite, upper stomach pain (that may spread to your back), nausea or vomiting, [fast heart rate](#), dark urine, jaundice (yellowing of the skin or eyes);
- **severe stomach problems**--severe stomach or chest pain, pain when swallowing, heartburn, diarrhea, rectal bleeding, bloody or tarry stools; or

- **increased pressure inside the skull**--severe headaches, ringing in your ears, dizziness, nausea, vision problems, pain behind your eyes.

Common side effects of isotretinoin may include:

- dryness of your skin, lips, eyes, or nose (you may have nosebleeds);
- vision problems;
- headache, back pain, joint pain, muscle problems;
- skin reactions; or
- [cold symptoms](#) such as stuffy nose, sneezing, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Isotretinoin side effects](#) (more detail)

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Warnings

Isotretinoin in just a single dose can cause severe birth defects or death of a baby. Never use isotretinoin if you are pregnant or able to become pregnant.

You must have a negative pregnancy test before taking isotretinoin. You will also be required to use two forms of [birth control](#) to prevent pregnancy while taking this medicine. **Stop using isotretinoin and call your doctor at once if you think you might be pregnant.**

Before taking this medicine

Isotretinoin can cause miscarriage, premature birth, severe birth defects, or death of a baby if the mother takes this medicine at the time of conception or during pregnancy. Even one dose of isotretinoin can cause major birth defects of the baby's ears, eyes, face, skull, heart, and brain. **Never use isotretinoin if you are pregnant or able to become pregnant.**

For Women: Unless you have had your uterus and ovaries removed (total [hysterectomy](#) with oophorectomy) or have been in menopause for at least 12 months in a row, you are **considered to be able to get pregnant**. You must have 2 negative pregnancy tests before you start taking isotretinoin, before each prescription is refilled, right after you take your

last dose of isotretinoin, and again 30 days later. All pregnancy testing is required by the iPLEDGE program.

You must agree in writing to use two specific forms of birth control beginning 30 days before you start taking isotretinoin and ending 30 days after your last dose. **Both a primary and a secondary form of birth control must be used together.**

Primary forms of birth control include:

- tubal ligation (tubes tied);
- vasectomy of the male sexual partner;
- an IUD (intrauterine device);
- estrogen-containing [birth control pills](#) (not mini-pills); and
- hormonal birth control patches, implants, injections, or [vaginal ring](#).

Secondary forms of birth control include:

- a male latex condom with or without spermicide;
- a diaphragm plus a spermicide;
- a cervical cap plus a spermicide; and
- a vaginal sponge containing a spermicide.

Stop using isotretinoin and call your doctor at once if you have unprotected sex, if you quit using birth control, if your period is late, or if you think you might be pregnant. If you get pregnant while taking isotretinoin, call the iPLEDGE pregnancy registry at 1-866-495-0654.

Not having sexual intercourse (abstinence) is the most effective method of preventing pregnancy.

You should not use isotretinoin if you are allergic to it.

Tell your doctor if you have ever had:

- depression or mental illness;
- asthma;
- [liver disease](#);
- diabetes;
- [heart disease](#) or [high cholesterol](#);
- [osteoporosis](#) or low bone mineral density;
- an eating disorder such as anorexia;
- a food or drug allergy; or
- an intestinal disorder such as [inflammatory bowel disease](#) or [ulcerative colitis](#).

Do not breastfeed.

Not approved for use by anyone younger than 12 years old.

How should I take isotretinoin?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Use the medicine exactly as directed.

Each prescription of isotretinoin must be filled within 7 days of the date it was written by your doctor. You will receive no more than a 30-day supply of isotretinoin at one time.

Always take isotretinoin with a full glass of water. Do not chew or suck on the capsule. Swallow it whole.

Follow all directions about taking isotretinoin with or without food.

Use isotretinoin for the full prescribed length of time. Your acne may seem to get worse at first, but should then begin to improve.

You may need frequent blood tests.

Never share this medicine with another person, even if they have the same symptoms you have.

Store at room temperature away from moisture, heat, and light.

Isotretinoin dosing information

Usual Adult Dose for Acne:

Maintenance dose: 0.25 to 0.5 mg/kg orally 2 times a day

Maximum dose: Up to 2 mg/kg/day

Duration of therapy: Up to 20 weeks

Comments:

- Patients should take some formulations of this drug with food.
- Prior to increasing the dose, patients should be asked about their compliance with treatment (e.g., taking this drug with food).
- Patients with very severe acne, scarring, or primary manifestations on the trunk may require 2 mg/kg/day dosing.
- Any patient requesting refills requires a new prescription and a new authorization from the iPLEDGE program.
- The safety and efficacy of once a day dosing has not been established; thus, once a day dosing is not recommended.

Use: Treatment of severe recalcitrant nodular acne in patients who are unresponsive to conventional therapy, including systemic antibiotics

Usual Pediatric Dose for Acne:

12 years or older:

-Maintenance dose: 0.25 to 0.5 mg/kg orally 2 times a day

-Maximum dose: 2 mg/kg/day

-Duration of therapy: Up to 20 weeks

Comments:

- Patients should take some formulations of this drug with food.
- Prior to increasing the dose, patients should be asked about their compliance with treatment (e.g., taking this drug with food).

- Patients with very severe acne, scarring, or primary manifestations on the trunk may require 2 mg/kg/day dosing.
- Any patient requesting refills requires a new prescription and a new authorization from the iPLEDGE program.
- The safety and efficacy of once a day dosing has not been established; thus, once a day dosing is not recommended.

Use: Treatment of severe recalcitrant nodular acne in patients who are unresponsive to conventional therapy, including systemic antibiotics

 [Detailed Isotretinoin dosage information](#)

What happens if I miss a dose?

Skip the missed dose and use your next dose at the regular time. **Do not** use two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. Overdose symptoms may include headache, dizziness, vomiting, stomach pain, warmth or tingling in your face, swollen or cracked lips, and [loss of balance](#) or coordination.

What should I avoid while taking isotretinoin?

Do not take a vitamin or mineral supplement that contains vitamin A, unless your doctor tells you to.

Do not donate blood while taking isotretinoin and for at least 30 days after you stop taking it. Donated blood that is later given to a pregnant woman could lead to birth defects in her baby if the blood contains any level of isotretinoin.

While you are taking isotretinoin and for at least 6 months after your last dose: Do not use wax hair removers or have dermabrasion or laser skin treatments. Scarring may result.

Isotretinoin could make you sunburn more easily. Avoid sunlight or tanning beds. Wear protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

Avoid driving or hazardous activity until you know how isotretinoin will affect you. Isotretinoin may impair your vision, especially at night.

What other drugs will affect isotretinoin?

Tell your doctor about all your other medicines, especially:

- phenytoin;
- [St. John's wort](#) (may make birth control pills less effective);
- vitamin or mineral supplements;
- progestin-only birth control pills (mini-pills, may not work as well when taken with isotretinoin);
- steroid medicine; or
- a [tetracycline](#) antibiotic, including [doxycycline](#) or [minocycline](#).

This list is not complete. Other drugs may affect isotretinoin, including prescription and over-the-counter medicines,

vitamins, and [herbal products](#). Not all possible [drug interactions](#) are listed here.

 [Isotretinoin drug interactions](#) (more detail)

Does isotretinoin interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

+

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Further information

- Your doctor pharmacist can provide more information about isotretinoin.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only


Pregnancy & Lactation

 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

 Drug history at FDA



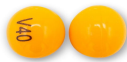
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