

MEDICATION GUIDE

ACCUTANE® (ACK-U-TANE)

(isotretinoin capsules)

Read the Medication Guide that comes with Accutane before you start taking it and each time you get a prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Accutane?

- Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Accutane can cause birth defects, Accutane is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE REMS.
- Accutane 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.

Patients who are pregnant or who plan to become pregnant must not take Accutane. **Patients must not get pregnant:**

- for 1 month before starting Accutane
- while taking Accutane
- for 1 month after stopping Accutane

If you get pregnant while taking Accutane, 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 Pregnancy Registry at 1-866-495-0654

2. Serious mental health problems. Accutane may cause:

- **depression**
- **psychosis** (seeing or hearing things that are not real)
- **suicide.** Some patients taking Accutane 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 Accutane 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 Accutane, you may also need follow-up mental health care if you had any of these symptoms.

What is Accutane?

Accutane 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. Accutane can cause serious side effects (see “What is the most important information I should know about Accutane?”).

Accutane can only be:

- prescribed by doctors that are enrolled in the iPLEDGE REMS
- dispensed by a pharmacy that is enrolled with the iPLEDGE REMS
- given to patients who are enrolled in the iPLEDGE REMS 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 Accutane?

- **Do not take Accutane if you are pregnant, plan to become pregnant, or become pregnant during Accutane treatment.** Accutane causes life-threatening birth defects. See “What is the most important information I should know about Accutane?”
- **Do not take Accutane if you are allergic to anything in it.** See the end of this Medication Guide for a complete list of ingredients in Accutane.

What should I tell my doctor before taking Accutane?

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. Accutane must not be used by patients 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.

Accutane 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 Accutane. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with Accutane 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 Accutane. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with Accutane may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with Accutane 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 Accutane 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 Accutane?

• You must take Accutane exactly as prescribed. You must also follow all the instructions of the iPLEDGE REMS. Before prescribing Accutane your doctor will:

- explain the iPLEDGE REMS to you
- have you sign the Patient Enrollment Form for Patients who cannot get Pregnant. Patients who can get pregnant must also sign another enrollment form.

You will not be prescribed Accutane if you cannot agree to or follow all the instructions of the iPLEDGE REMS.

- You will get no more than a 30-day supply of Accutane at a time. This is to make sure you are following the Accutane iPLEDGE REMS. You should talk with your doctor each month about side effects.
- The amount of Accutane you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take Accutane 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your Accutane capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Accutane 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 two doses at the same time.
- If you take too much Accutane or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking Accutane. 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 Accutane. Patients who can get pregnant will get a pregnancy test each month.
- Patients who can get pregnant must agree to use two separate forms of effective birth control at the same time one month before, while taking, and for one month after taking Accutane. **You must access the iPLEDGE REMS system to answer questions about the program requirements and to enter your two chosen forms of birth control.** To access the iPLEDGE REMS system, go to www.ipledgeprogram.com or call 1-866-495-0654.

You must talk about effective birth control forms 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 Accutane.

If you have sex at any time without using two forms of effective birth control, get pregnant, or miss your expected period, stop using Accutane and call your doctor right away.

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What should I avoid while taking Accutane?

- **Do not get pregnant** while taking Accutane and for one month after stopping Accutane. See **“What is the most important information I should know about Accutane?”**
- **Do not breast feed** while taking Accutane and for one month after stopping Accutane. We do not know if Accutane can pass through your milk and harm the baby.
- **Do not give blood** while you take Accutane and for one month after stopping Accutane. If someone who is pregnant gets your donated blood, their baby may be exposed to Accutane and may be born with birth defects.
- **Do not take other medicines or herbal products** with Accutane unless you talk to your doctor. See **“What should I tell my doctor before taking Accutane?”**
- **Do not drive at night until you know if Accutane has affected your vision.** Accutane 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 Accutane and for at least 6 months after you stop.** Accutane 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. Accutane may make your skin more sensitive to light.
- **Do not share Accutane with other people.** It can cause birth defects and other serious health problems.

What are the possible side effects of Accutane?

- **Accutane 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 Accutane?”**
- **Accutane may cause serious mental health problems.** See **“What is the most important information I should know about Accutane?”**

- **serious brain problems.** Accutane can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking Accutane 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 Accutane. In some patients a rash can be serious. Stop using Accutane and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like “pink eye”), a rash with a 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 Accutane. Stop taking Accutane 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.** Accutane 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 Accutane. Tell your doctor if you get:

- back pain
- joint pain
- broken bone. Tell all healthcare providers that you take Accutane if you break a bone.

Stop Accutane 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.

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

- **hearing problems.** Stop using Accutane 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.** Accutane may affect your ability to see in the dark. This condition usually clears up after you stop taking Accutane, but it may be permanent. Other serious eye effects can occur. Stop taking Accutane 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 Accutane and after treatment.

- **lipid (fats and cholesterol in blood) problems.** Accutane 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 Accutane treatment is finished.

- **serious allergic reactions.** Stop taking Accutane and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking Accutane and call your doctor if you get a fever, rash, or red patches or bruises on your legs.

- **blood sugar problems.** Accutane 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 Accutane** 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 Accutane. 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 or JG Pharma, Inc. at 1-844-325-3350.

How should I store Accutane?

- Store Accutane at 68° to 77°F (20° to 25°C). Protect from light.
- **Keep Accutane and all medicines out of the reach of children.**

General Information about Accutane

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use Accutane for a condition for which it was not prescribed. Do not give Accutane to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Accutane. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Accutane that is written for healthcare professionals.

You can also call iPLEDGE REMS at 1-866-495-0654 or visit www.ipledgeprogram.com.

What are the ingredients in Accutane?

Active Ingredient: isotretinoin USP

Inactive Ingredients: butylated hydroxyanisole, edetate disodium, hydrogenated vegetable oil (Type-I and Type-II), medium chain triglyceride, refined soybean oil and white wax. Gelatin capsules contain ferric oxide red, ferric oxide yellow (for 30 mg), gelatin, glycerin, methylparaben, propyl paraben, lake blend blue (LB-332) containing D&C Yellow No.10, FD&C Blue No.1 (for 10 mg), lake blend red (LB-1574) containing D&C Red No.27, D&C Red No.30 (for 20 mg), lake blend green (LB-333) containing D&C Yellow No.10, FD&C Blue No.1 (for 40 mg), lake blend white (TLB-1774) containing FD&C Blue No.2, titanium dioxide, and opacode black S-1-17823 containing iron oxide black, N-butyl alcohol, propylene glycol, ammonium hydroxide and shellac.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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