

MEDICATION GUIDE

ABSORICA[®] (AB-SORE-I-KAH) (isotretinoin) capsules

Read the Medication Guide that comes with ABSORICA 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 ABSORICA?

- ABSORICA is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because ABSORICA can cause birth defects, ABSORICA is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- ABSORICA 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.** Females who are pregnant or who plan to become pregnant must not take ABSORICA. **Females must not get pregnant:**

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

If you get pregnant while taking ABSORICA, 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.** ABSORICA may cause:

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

What is ABSORICA?

ABSORICA 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. ABSORICA can cause serious side effects (see “**What is the most important information I should know about ABSORICA?**”). ABSORICA can only be:

- prescribed by doctors 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.

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 ABSORICA?

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

What should I tell my doctor before taking ABSORICA?

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. ABSORICA must not be used by females who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements. ABSORICA 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 ABSORICA. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with ABSORICA 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 ABSORICA. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with ABSORICA may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with ABSORICA 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 ABSORICA 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 ABSORICA?

- You must take ABSORICA exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing ABSORICA, your doctor will:
 - explain the iPLEDGE Program to you
 - have you sign the Patient Information/Informed Consent form (for all patients). Females who can get pregnant must also sign another consent form.

You will not be prescribed ABSORICA 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 ABSORICA at a time. This is to make sure you are following the ABSORICA iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of ABSORICA you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take ABSORICA 2 times a day without regard to meals, unless your doctor tells you otherwise. **Swallow your ABSORICA capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** ABSORICA 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 ABSORICA or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking ABSORICA. 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 ABSORICA. Females who can get pregnant will get a pregnancy test each month.
- Females 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 ABSORICA. **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.

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 ABSORICA.

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

What should I avoid while taking ABSORICA?

- **Do not get pregnant** while taking ABSORICA and for one month after stopping ABSORICA. See “**What is the most important information I should know about ABSORICA?**”
- **Do not breast feed** while taking ABSORICA and for one month after stopping ABSORICA. We do not know if ABSORICA can pass through your milk and harm the baby.

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

What are the possible side effects of ABSORICA?

- **ABSORICA 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 ABSORICA?**”
- **ABSORICA may cause serious mental health problems.** See “**What is the most important information I should know about ABSORICA?**”
- **serious brain problems.** ABSORICA can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking ABSORICA 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 ABSORICA. In some patients a rash can be serious. Stop using ABSORICA 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 ABSORICA. Stop taking ABSORICA 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.** ABSORICA 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 ABSORICA. Tell your doctor if you get:
 - back pain
 - joint pain
 - broken bone. Tell all healthcare providers that you take ABSORICA if you break a bone.

Stop ABSORICA 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.

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

- **hearing problems.** Stop using ABSORICA 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.** ABSORICA may affect your ability to see in the dark. This condition usually clears up after you stop taking ABSORICA, but it may be permanent. Other serious eye effects can occur. Stop taking ABSORICA 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 ABSORICA and after treatment.
- **lipid (fats and cholesterol in blood) problems.** ABSORICA 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 ABSORICA treatment is finished.
- **serious allergic reactions.** Stop taking ABSORICA and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking ABSORICA and call your doctor if you get a fever, rash, or red patches or bruises on your legs.

- **blood sugar problems.** ABSORICA 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 ABSORICA** 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.

ABSORICA contains the color additive FD&C Yellow No. 5 (tartrazine) which may cause allergic type reactions, including asthma in some people. The overall occurrence of allergic reaction is low. This reaction is most often seen in people who also have an allergy to aspirin.

These are not all of the possible side effects of ABSORICA. 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 Sun Pharmaceutical Industries, Inc. at 1-800-818-4555.**

How should I store ABSORICA?

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

General Information about ABSORICA

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use ABSORICA for a condition for which it was not prescribed. Do not give ABSORICA 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 ABSORICA. If you would like more information, talk with your doctor.

You can ask your doctor or pharmacist for information about ABSORICA that is written for health care professionals. You can also call iPLEDGE Program at 1-866-495-0654 or visit www.ipledgeprogram.com.

What are the ingredients in ABSORICA?

Active ingredient: Isotretinoin, USP

Inactive ingredients: Propyl gallate, sorbitan monooleate, soybean oil and stearyl polyoxyglycerides. Gelatin capsules contain the following dye systems: 10 mg – iron oxide (yellow) and titanium dioxide; 20 mg – iron oxide (red) and titanium dioxide; 25 mg – FD&C Blue #1, FD&C Yellow #5 (**tartrazine**), FD&C Yellow #6 and titanium dioxide; 30 mg – iron

oxide (black, red and yellow) and titanium dioxide; 35 mg – FD&C Blue #2, iron oxide (black, red and yellow) and titanium dioxide; and 40 mg – iron oxide (black, red and yellow) and titanium dioxide.

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