Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

ISOtretinoin (Systemic

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Absorica; Absorica LD; Accutane; Amnesteem; Claravis; Myorisan [DSC]; Zenatane

Brand Names: Canada

Absorica LD; Accutane; ALTI-Isotretinoin; Clarus; Epuris

Warning

- Do not take if you are pregnant or may get pregnant. The risk of severe and sometimes deadly birth defects is very high if you take this drug at any time while you are pregnant. Any unborn baby can be harmed. There is no good way to tell if an unborn baby has been harmed. The risk of losing an unborn baby is also raised, and premature births have happened. Talk with your doctor before you start this drug. If you know all the facts and can follow how to take this drug, you must sign a patient fact/consent form. Do not sign the form and do not take this drug if you do not know everything on the form.
- You must have 2 pregnancy tests that show you are NOT pregnant before starting this drug. You must have pregnancy tests done while taking this drug. Talk with your doctor.
- You must either use 2 kinds of birth control or commit to not having any sex that could cause pregnancy while taking this drug. You must do this for 1 month before starting this drug, during treatment, and for at least 1 month after the last dose. Talk about this with your doctor.
- If you get pregnant while taking this drug or within 1 month after your last dose, call your doctor right away.

What is this drug used for?

- It is used to treat pimples (acne).
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are able to get pregnant and are not using 2 kinds of birth control.

- If you are planning to get pregnant within 1 month before treatment, during treatment, or within 1 month after your last dose.
- If you are taking any of these drugs: Demeclocycline, doxycycline, minocycline, tetracycline, a product that has vitamin A in it, a product that is like vitamin A, or St. John's wort.
- If you are breast-feeding. Do not breast-feed for some time after getting this drug. Talk with your doctor to see how long to avoid breast-feeding after getting this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert or have clear eyesight until you see how this drug affects you.
- Lowered night eyesight may happen. This may be sudden. This may clear up after you stop the drug but sometimes it may not go away.
- Use care when driving at night or doing other tasks in lowered lighting.
- Do not donate blood while using this drug and for 1 month after stopping.
- Treatment with this drug may lead to higher cholesterol and triglycerides. The effect of these changes on heart health is not known. Talk with the doctor.
- Have your blood work and bone density checked as you have been told by your doctor.

- You may get sunburned more easily. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your blood sugar as you have been told by your doctor.
- If your weight changes, talk with your doctor. The dose of this drug may need to be changed.
- Skin may look worse before it looks better.
- Talk with your doctor before you drink alcohol.
- If you are allergic to tartrazine (FD&C Yellow No. 5), talk with your doctor. Some products have tartrazine.
- Avoid cosmetic skin treatments like waxing, dermabrasion, or laser treatments during treatment and for at least 6 months after the last dose. The chance of scarring may be increased.
- This drug may cause weak bones and tendon problems in some people. The chance of bone problems like broken bones may be raised in people who play certain sports. Talk with the doctor.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- Do not use progestin-only birth control pills (minipills). They may not work well. Talk with your doctor.
- If you have sex without using 2 kinds of birth control within 1 month before starting this drug, during treatment, or within 1 month after your last dose, call your doctor right away. If you think you may be pregnant or if you miss your period, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of depression, suicidal thoughts, emotional ups and downs, abnormal thinking, anxiety, or lack of interest in life.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of esophagus problems like chest pain, trouble swallowing, pain when swallowing, or new or worse heartburn.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Behavior problems.
- Change in eyesight, eye pain, or severe eye irritation.
- Back, bone, joint, or muscle pain.
- Muscle weakness.
- Any unexplained bruising or bleeding.
- Feeling very tired or weak.
- Not able to pass urine or change in how much urine is passed.
- Swelling.
- Swollen gland.

- Fast or abnormal heartbeat.
- Hearing problems like change in hearing or ringing in the ears may happen. This may go away after stopping the drug but sometimes it may not.
- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- Severe and sometimes deadly pancreas problems (pancreatitis) have happened with this drug. Call your doctor right away if you have severe stomach pain, severe back pain, or severe upset stomach or throwing up.
- Low white blood cell counts have happened with this drug. This may lead to a higher chance of getting an infection. Call your doctor right away if you have signs of infection like fever, chills, or sore throat.
- Raised pressure in the brain has happened with this drug. This can cause long lasting loss of eyesight and sometimes death. Call your doctor right away if you have a bad headache, dizziness, upset stomach or throwing up, or seizures. Call your doctor right away if you have weakness on 1 side of the body, trouble speaking or thinking, change in balance, or change in eyesight.
- Severe bowel problems may happen with this drug (inflammatory bowel disease). Tell your doctor right away if you have signs like severe diarrhea, stomach pain, bleeding from the rectum, or rectal pain. This may clear up after you stop the drug but sometimes it may not go away.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dry mouth, skin, or eyes.
- Dry lips.

- Nose or throat irritation.
- Change in how contact lenses feel in the eyes.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Some drugs may need to be taken with food or on an empty stomach. For some drugs it does not matter. Check with your pharmacist about how to take this drug.
- Swallow whole. Do not break, chew, crush, or suck on the capsules.
- Take with a full glass of liquid.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- You will get a month's supply of this drug at a time.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature protected from light. Store in a dry place. Do not store in a bathroom.

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options,

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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