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 give this drug to your child during pregnancy or if your child may get pregnant. The risk of severe and sometimes deadly birth defects is very high if your child takes this drug at any time during pregnancy. 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 the doctor before your child starts this drug. If you and your child know all the facts and your child can follow how to take this drug, a patient fact/consent form must be signed. The form must not be signed and your child must not take this drug if you and your child do not know everything on the form.

- Two (2) pregnancy tests must be done to show that your child is not pregnant before starting this drug. Your child will need a pregnancy test every month in order to get more of this drug. Talk with the doctor.
- Your child must either use 2 kinds of birth control or commit to not having any sex that could cause pregnancy while taking this drug. Your child 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 the doctor.
- If your child gets pregnant while taking this drug or within 1 month after the last dose, call the doctor right away.

What is this drug used for?

- It is used to treat pimples (acne).
- It may be given to your child for other reasons. Talk with

the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child is able to get pregnant and is not using 2 kinds of birth control.
- If your child is planning to get pregnant within 1 month before treatment, during treatment, or within 1 month after the last dose.
- If your child is 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 your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby for some time after she gets this drug. Talk with your child's doctor to see how long your child needs 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 the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child avoid tasks or actions that call for alertness or clear eyesight until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.
- Lowered night eyesight may happen. This may be sudden. This may clear up after your child stops the drug but sometimes it may not go away. Have your child use care when doing tasks that call for clear eyesight.
- Be sure your child does 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 child's blood work and bone density checked as you have been told by the doctor.
- Your child may get sunburned more easily. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and dress your child in clothing and eyewear that protects from the sun.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your child's blood sugar as you have been told by the doctor.
- If your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.
- Skin may look worse before it looks better.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- If your child is allergic to tartrazine (FD&C Yellow No. 5), talk with your child's doctor. Some products have tartrazine.
- Have your child 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.

If your child is or may be sexually active:

- Do not have your child use progestin-only birth control pills (minipills). They may not work well. Talk with the doctor.
- If your child has sex without using 2 kinds of birth control within 1 month before starting this drug, during treatment, or within 1 month after the last dose, call the doctor right away. If you think your child may be pregnant or if your child misses a period, call the doctor right away.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 your child has signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in the mouth, throat, nose, or eyes.
- Severe and sometimes deadly pancreas problems (pancreatitis) have happened with this drug. Call your child's doctor right away if your child has 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 child's doctor right away if your child has 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 the doctor right away if your child has a bad headache, dizziness, upset stomach or throwing up, or seizures. Call the doctor right away if your child has a change in strength on 1 side that is greater than the other, trouble speaking or thinking, change in balance, or blurred eyesight or other change in eyesight.
- Severe bowel problems may happen with this drug (inflammatory bowel disease). Tell the doctor right away if your child has signs like severe diarrhea, stomach pain, bleeding from the rectum, or rectal pain. This may clear up after your child stops 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 child's doctor or get medical help if any of these side

effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Some drugs may need to be given with food or on an empty stomach. For some drugs, it does not matter. Check with your pharmacist about how to give this drug to your child.
- Have your child swallow whole. Do not let your child break, chew, crush, or suck on the capsules.
- Give this drug with a full glass of liquid.

- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- You will get a month's supply of this drug at a time.

What do I do if my child misses a dose?

- Skip the missed dose and go back to your child's normal time.
- Do not give 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.

- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, 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.

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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, including any

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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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