PATIENT & CAREGIVER EDUCATION

Palovarotene

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

Sohonos

Brand Names: Canada

Sohonos

Warning

- Do not take this drug if you are pregnant. Use during pregnancy may cause birth defects or loss of the unborn baby.
- A pregnancy test will be done to show that you are NOT pregnant before starting this drug and while taking it.
- If you may become pregnant, you will need to use birth control for 1 month before starting this drug, during treatment, and for 1 month after your last dose. If you only take this drug as needed for flare-ups, you will need to use birth control all the time. Be sure you know what type of birth control to use and when to use it. If you are not sure, talk with your doctor.
- If you get pregnant while taking this drug or within 1 month after your last dose, call your doctor right away.
- This drug can cause changes in bone growth. This may cause children to stop growing. Children need regular growth checks while taking this drug.

What is this drug used for?

- It is used to lessen the growth of bone where it does not normally grow in people with fibrodysplasia ossificans progressive (FOP).

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 have any of these health problems: Kidney disease or liver disease.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.

- If you take any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like certain drugs that are used for HIV, infections, seizures, and others. There are many drugs that must not be taken with this drug.
- If you are able to get pregnant and are not using birth control.
- If you are breast-feeding. Do not breast-feed while you take this drug or for 1 month after your last dose.

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?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- 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.
- This drug may cause weak bones or bone thinning. This can increase the risk for a broken bone.
- Have your blood work and other lab tests checked as you have been told by your doctor. This includes X-rays of the spine.
- Be sure the capsules are not touched by someone who is pregnant or able to get pregnant.
- 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.

- It is common to have dry eyes with this drug. Artificial tears, lubricant eye gels, or other products may be used to prevent or treat dry eyes. If you have questions, talk with the doctor or pharmacist.
- Avoid grapefruit and grapefruit juice.
- Avoid other sources of vitamin A.
- Do not donate blood while taking this drug or for 1 week after stopping.

Children:

- This drug may not be for use in children of all ages. Talk with the doctor before giving this drug to a child.
- If your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

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 skin infection like oozing, heat, swelling, redness, or pain.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Swelling in the arms or legs.
- Change in nails.
- Bone pain.

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 eyes.
- Dry mouth.
- Upset stomach.
- Back, muscle, or joint pain.
- Headache.
- Pain in arms or legs.
- Feeling tired or weak.
- It is common to have skin irritation with this drug. This includes dry skin; dry, scaly, or chapped lips; hair loss; itching; redness of the skin; rash; skin peeling; and eczema. This may also raise the risk of skin infections. Ask the doctor or pharmacist for ways to prevent or treat skin irritation. Call your doctor if any of these effects are severe, bother you, or do not go away.

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.

- Take this drug with food.
- Take this drug at the same time of day.

- Swallow whole. Do not chew or crush.
- If needed, you may open the capsule and sprinkle the contents on 1 teaspoon (5 mL) of soft food like applesauce, low-fat yogurt, or warm oatmeal. Do not mix with grapefruit, pomelo, or juices that have these fruits in them. Swallow the mixture within 1 hour after mixing. Protect the mixture from sunlight; do not store for future use.
- If someone else is giving you this drug, be sure that person wears gloves to avoid contact with this drug.
- If you open the capsule, use paper towels and a sealable container (like a sealable bag) to collect and throw away any waste.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it has been more than 6 hours since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses on the same day.

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

- Store at room temperature in a dry place. Do not store in a bathroom.
- Store in the outer carton to protect from light.
- 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, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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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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