

# iMedix: Your Personal Health Advisor.

## Sohonos 10 Mg Capsule

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### Description

Side Effects Headache, bone/joint pain, hair loss, dry mouth, dry eyes, dry lips/skin, or other skin changes may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To relieve dry eyes, you may use a lubricating eye ointment or tear replacement eye drops. Ask your pharmacist for details. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as depression, anxiety, thoughts of suicide), vision changes (such as blurred/double vision, decreased vision). A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses Palovarotene is used to treat a certain rare genetic problem (fibrodysplasia ossificans progressiva-FOP). It works by reducing bone formation in muscles and tendons that can be caused by FOP. Palovarotene belongs to a class of drugs known as retinoids, which are related to vitamin A. How to use Sohonos 10 Mg Capsule Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start taking palovarotene and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth as directed by your doctor, usually once daily with food. Swallow the capsules whole. Do not crush or chew the capsules. The dosage is based on your medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). For children, the dosage is also based on weight. This medication can be used for long-term treatment (chronic) or for short-term attacks (flares). Do not take both chronic and flare treatment at the same time. If you are having trouble swallowing the capsule, you may open the capsule and carefully sprinkle its contents onto a teaspoonful of soft food (such as applesauce, yogurt, pudding, milk, oatmeal, rice cereal, liquid nutritional supplement) just before you take it. Swallow all of the drug/food mixture right away. The mixture may also be swallowed within an hour if it is kept at room temperature, away from direct sunlight. If you are opening the capsules, wash your hands before

and after handling the medication. You and/or your caregiver should wear disposable gloves when handling this medication. If powder from the capsule spills, wipe it up right away with a wet paper towel and throw away in a closed container, such as a plastic bag. Clean the spill area right away with soap and water. Make sure not to breathe the powder from the capsules. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase. Avoid eating grapefruit or drinking grapefruit juice while using this medication unless your doctor or pharmacist says you may do so safely. Grapefruit can increase the chance of side effects with this medicine. Ask your doctor or pharmacist for more details. Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the capsules. Tell your doctor if you do not get better or get worse (including new flares). **Warnings** Women who are pregnant must not use palovarotene. Women must avoid becoming pregnant while taking this medication and for one month after stopping treatment. It can cause serious (even fatal) birth defects, miscarriage, or premature birth of the baby. Talk with your doctor about the risks and benefits of taking this medication and your birth control options. Women who are able to have children must use one or two reliable forms of birth control for 1 month before starting palovarotene, during use, and for at least 1 month after the last dose. If you are going to use only one form of birth control (instead of using two), it must be one that is highly effective, such as an intrauterine device (IUD). Consult your doctor for more details. Women who are able to have children must also meet the following requirements: test negative on a pregnancy test before starting treatment, have monthly pregnancy tests during treatment, and one month after the last dose. This medication may stop normal growth in children. Your doctor will regularly monitor your child during treatment. Tell your doctor right away if you notice your child not growing (decreased height) or differences in the way they walk. **Interactions** Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug are: tetracycline antibiotics, vitamin A, other retinoid drugs (such as acitretin, alitretinoin). Other medications can affect the removal of palovarotene from your body, which may affect how palovarotene works. Examples include azole antifungals (such as ketoconazole, itraconazole), macrolide antibiotics (such as clarithromycin), rifamycins (such as rifampin), St. John's wort, among others. **Precautions** Before taking palovarotene, tell your doctor or pharmacist if you are allergic to it; or to vitamin A-related drugs (other retinoids such as isotretinoin); or if you have any other allergies. This product may contain inactive ingredients (such as lactose), which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, mental/mood problems (such as depression), bone loss conditions (such as osteoporosis/osteomalacia, decreased bone density). Do not donate blood while you are taking this medication and for at least 1 week after you stop taking it. This will prevent the possibility of your blood being given to a pregnant woman. This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness. Palovarotene may cause vision changes, including decreased night vision. Do not drive, use machinery, or do any activity that requires clear vision (especially at night) until you can do it safely. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Your doctor may start you on treatment to prevent flares before surgery, vaccinations, or other illnesses. Consult your doctor for more details. This medication must not be used during pregnancy. It may harm an unborn baby. Discuss with your doctor the use of one or two reliable forms of birth control (such as condoms, birth control pills, intrauterine devices) for 1 month before starting palovarotene, during use, and for at least 1 month after the last dose. If you become pregnant or think you may be pregnant, tell your doctor right away. Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the capsules. It is unknown if this drug passes into breast milk. Because of the possible risk to the infant, breastfeeding while using this drug and for 1 month after the last dose is not recommended. Consult

your doctor before breast-feeding. **Overdose** If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Do not share this medication with others. Lab and/or medical tests (such as x-rays, height measurement, liver/kidney function) must be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it as soon as you remember unless it is more than 6 hours after the time you usually take the dose. In that case, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from moisture. Keep the blister packages in the original carton to protect from light. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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## **Side Effects**

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## **Uses**

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## **Interactions**

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## **Other Details**

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