

MEDICATION GUIDE
SOHONOS [so-ho-nos]
(palovarotene capsules)

What is the most important information I should know about SOHONOS?

- **SOHONOS can cause birth defects (deformed babies) if taken during pregnancy. Females who are pregnant or who plan to become pregnant must not take SOHONOS.**

Females who can become pregnant:

- Your healthcare provider will ask you to take a pregnancy test 1 week before starting treatment with SOHONOS, periodically during treatment, and 1 month after you stop treatment with SOHONOS.
- You must use effective birth control (contraception) starting at least 1 month before starting treatment with SOHONOS, during treatment and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.
- If you become pregnant or think you may be pregnant during treatment with SOHONOS, stop taking SOHONOS and call your healthcare provider right away.

Because SOHONOS can cause birth defects, SOHONOS is only for people who can understand and agree to carry out all instructions for pregnancy prevention.

- **SOHONOS can cause bone growth changes.** Children may stop growing while taking SOHONOS. Bone growth changes such as permanent early closure of the growth plate in growing children have happened with SOHONOS. Your healthcare provider will closely monitor your child's bone growth and height during treatment with SOHONOS.

What is SOHONOS?

- SOHONOS is a prescription medicine used to reduce the amount of new heterotopic ossification in adults and children 8 years of age and older for females and 10 years of age and older for males with fibrodysplasia ossificans progressiva (FOP).
- SOHONOS is not recommended for females younger than 8 years of age or males younger than 10 years of age.

Do not take SOHONOS if you:

- are pregnant. (See **“What is the most important information I should know about SOHONOS?”**)
- are allergic to medicines known as retinoids or any of the ingredients in SOHONOS. See the end of this Medication Guide for a complete list of ingredients in SOHONOS.

Before taking SOHONOS, tell your healthcare provider about all your medical conditions, including if you:

- have bone loss (osteoporosis), weak bones or any other bone problems.
- have or had mental health problems.
- have or have had kidney problems.
- have or have had liver problems.
- are breastfeeding or plan to breastfeed. It is not known if SOHONOS passes into your breastmilk. Breastfeeding is not recommended during treatment with SOHONOS and for at least 1 month after the last dose of SOHONOS. Talk to your healthcare provider about the best way to feed your baby if you take SOHONOS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOHONOS and certain other medicines can interact with each other, sometimes causing serious side effects.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take SOHONOS?

- Take SOHONOS exactly as your healthcare provider tells you.
- Take SOHONOS capsules whole with food. If you are unable to swallow the capsule, the capsule contents may be emptied onto a teaspoon (5 mL) of soft food (such as apple sauce, low-fat yogurt, or warm oatmeal) and taken within 1 hour of opening.
- Take SOHONOS at about the same time each day.
- Do not eat grapefruit or drink grapefruit juice during treatment with SOHONOS. Grapefruit may increase the levels of SOHONOS in your blood.
- If you miss a dose of SOHONOS, take it as soon as you remember. If the dose has been missed by more than 6 hours, the missed dose should be skipped, and next dose should be taken at the regular time. **Do not** take two doses at the same time or in the same day.
- Your healthcare provider may change your dose of SOHONOS as needed if you get certain side effects.
- If you take more SOHONOS than prescribed you may have symptoms such as severe headache, nausea or vomiting, drowsiness, irritability, and itching.

What should I avoid while taking SOHONOS?

- Do not get pregnant while taking SOHONOS. See “**What is the most important information I should know about SOHONOS?**”
- Avoid excessive exposure to sunlight and ultraviolet lights (e.g., tanning machines). SOHONOS may make your skin more sensitive to sunlight and ultraviolet light and you may burn more easily. You should use sunscreen and wear sunglasses and protective clothing that covers your skin to help protect against sunburn if you must be in the sunlight during treatment with SOHONOS.
- Avoid driving at night until you know if SOHONOS has affected your vision. SOHONOS may decrease your ability to see in the dark.
- Do not donate blood while taking SOHONOS and for 1 week after stopping SOHONOS.

What are possible side effects of SOHONOS?

SOHONOS can cause serious side effects, including:

- See “**What is the most important information I should know about SOHONOS?**”
- **skin-related problems.** SOHONOS may cause skin-related problems including dry skin, lips and eyes, hair loss, itching, redness, rash, and skin peeling. You may be at increased risk of developing skin and soft tissue infections while taking SOHONOS. If you develop these symptoms, your healthcare provider may tell you to use a moisturizer, sunscreen, or artificial tears.
- **bone mineral density problems.** SOHONOS can cause a reduction in bone mineral density (bone thinning) which can increase the risk of fractures in adults and children. Your healthcare provider should check you for this during treatment with SOHONOS.
- **new or worsening mental health problems.** SOHONOS may cause new or worsening mental health problems that include depression, anxiety, mood changes, and suicidal thoughts and behaviors. If you have a history of mental health problems, you may be at a higher risk of developing these side effects. Call your healthcare provider if you develop new or worsening mental health symptoms during treatment with SOHONOS. Your healthcare provider should monitor you for signs of depression and refer you for appropriate treatment, if necessary.
- **vision problems. Decreased vision in the dark (night blindness).** You may have difficulty seeing at night or in low lit areas. Your healthcare provider should send you to see an eye specialist if you experience vision problems.

The most common side effects of SOHONOS include:

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|-------------------|--|
| • dry skin | • swelling and small cracks in corner of the mouth |
| • dry lips | • nausea |
| • hair loss | • muscle and joint pain |
| • itching | • dry eyes |
| • redness | • headache |
| • rash | • fatigue |
| • skin peeling | |
| • drug eruption | |
| • skin irritation | |

These are not all the possible side effects of SOHONOS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SOHONOS?

- Store SOHONOS at room temperature between 68° to 77°F (20° to 25°C) in the original carton to protect from light.
- **Keep SOHONOS and all medicines out of the reach of children.**

General information about the safe and effective use of SOHONOS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SOHONOS for a condition for which it was not prescribed. Do not give SOHONOS to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SOHONOS that is written for healthcare professionals.

What are the ingredients in SOHONOS?

Active ingredient: palovarotene

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. The capsule consists of gelatin and titanium dioxide. The black printing ink consists of black iron oxide, potassium hydroxide, propylene glycol, and Shellac.

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For more information about SOHONOS, call 855-463-5127 or go to www.SOHONOS.com or drugsafety.USA@ipsen.com

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