



Getting started on **SOHONOS[®]** (palovarotene capsules)

For complete safety information about SOHONOS[®],
please refer to the Patient Medication Information
leaflet provided with your SOHONOS[®] prescription.

This guide was developed to help you get started on SOHONOS®, a medication your doctor has prescribed to help treat fibrodysplasia ossificans progressiva, otherwise known as FOP.

Read on for helpful information about SOHONOS®, including instructions on how to take SOHONOS®. At the end of this guide, you will find a notes section where you can keep track of any questions you may have, or how you are doing between doctor's visits.

If you need more information at any time, ask your prescribing doctor or nurse, or call 1-855-215-2288 and press 2 to speak to a SOHONOS® representative from the IPSEN CARES® program (Monday to Friday, 9 a.m. to 6 p.m. ET).

About SOHONOS®

SOHONOS® contains palovarotene, which belongs to a group of medications called retinoids. It works by preventing bone formation in muscles, tendons, or soft tissue.

What is SOHONOS® used for?

SOHONOS® is used to reduce the formation of extra bone in the muscles, tendons, and soft tissues – known as heterotopic ossification – in adults and children (females 8 years of age and older; males 10 years of age and older) with a rare condition known as fibrodysplasia ossificans progressiva or FOP.

Before your first dose of SOHONOS®

What should I tell my prescribing doctor?

Tell your prescribing doctor about any health conditions or problems you may have, including if you:

- Are pregnant, think you may be pregnant, or are planning to have a baby.
- Are breastfeeding.
- Have liver problems.
- Have kidney problems.
- Have risk factors for fractures, such as:
 - A history of fractures.
 - Osteoporosis (thin, fragile bones) or any other bone problems.
- Have an intolerance to some sugars. This is because SOHONOS® contains lactose.

What else should I tell them?

Tell your prescribing doctor about all the medications you are taking, including any drugs, vitamins, minerals, natural supplements, or alternative medications.

The following may interact with SOHONOS®:

- Medicines or vitamin supplements containing Vitamin A or other medicines derived from Vitamin A used for skin conditions, known as “retinoids” such as acitretin, alitretinoin, isotretinoin, tretinoin, adapalene, and tazarotene. Vitamin A in high doses has many of the same side effects as SOHONOS®. Taking both together may increase your chance of experiencing side effects.
- Medications used to treat fungal infections (antifungals), such as itraconazole, ketoconazole, and fluconazole.
- Medications used to treat bacterial infections (antibiotics) such as erythromycin, clarithromycin, rifampicin/rifampin, and tetracyclines.
- Medicines called “protease inhibitors” used to treat human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) or COVID-19 infection.
- Medications used to treat depression.
- Medications used to treat epilepsy or seizures such as phenytoin and carbamazepine.
- Herbal preparations containing St. John’s Wort extract (*Hypericum perforatum*), sometimes used for treating depression or depression-related conditions such as anxiety.

Treatment with SOHONOS[®]

How is SOHONOS[®] taken?



SOHONOS[®] is a capsule that is taken orally.

SOHONOS[®] will be prescribed by your doctor, who will determine the dose you will need to take daily. This may depend on your age, weight, and symptoms.

Do NOT change your SOHONOS[®] dose or the way you take your medication before discussing it with your prescribing doctor.



The recommended SOHONOS[®] dosage regimen is a combination of:

- Chronic treatment: treatment taken daily; and
- Flare-up treatment: higher-dose treatment protocol taken daily at the time of a flare-up.

Do NOT take both chronic and flare-up treatment at the same time. Your prescribing doctor will determine which treatment to follow.

Ensure you consult your prescribing doctor about the right dose for you.



Swallow whole with food (after a meal), preferably at the same time each day.



You should avoid ingesting grapefruit or products containing grapefruit for as long as you are using SOHONOS[®], as it may increase the amount of SOHONOS[®] in your blood.



If you are unable to swallow capsules:

- Open the capsules and sprinkle their contents onto a teaspoon of soft food (such as applesauce, yogurt, or pudding).
- Swallow the mixture. If you want to take it later, the mixture can be stored for up to 1 hour at room temperature provided that it is not exposed to direct sunlight.

Take SOHONOS[®] exactly as prescribed by your doctor. Check with them if you are unsure.

Treatment with SOHONOS®

What if I accidentally take more than the recommended dose of SOHONOS®?

Contact a doctor, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What if I miss a dose?

- If you miss a dose and it is within 6 hours of when it should have been taken, take the dose immediately. Take the next dose at the usual time.
- If you miss a dose by more than 6 hours, skip the missed dose. Continue with the next scheduled dose at the usual time.
- Do NOT take two doses at the same time or in the same day to make up for a missed dose.

How do I store SOHONOS®?

Store SOHONOS® at room temperature (15°C to 30°C). Keep the blister strip in the carton in order to protect from light. Keep out of reach and sight of children.

Instructions for handling SOHONOS®:

- If you are pregnant or are planning to become pregnant, you should avoid contact with SOHONOS®.
- **For caregivers** emptying the capsule contents onto soft food:
 - Wear disposable gloves to avoid unintended exposure.
 - Use disposable paper towels and a container (e.g., a resealable bag) to collect waste.

Safety Information

Serious Warnings and Precautions

- SOHONOS® should only be prescribed by doctors who are knowledgeable in the:
 - use and monitoring of types of medicines called systemic retinoids.
 - risk of teratogenicity (potential to cause birth defects during pregnancy) in women who can become pregnant.

- SOHONOS® can cause bone growth to stop early in growing children. This may lead to possible short stature and differences in arm or leg length. Your prescribing doctor will explain the risks to you or your caregiver. Children who are actively growing should be closely monitored (every 3 months or as determined by their prescribing doctor) during treatment with SOHONOS®.
- SOHONOS® cause birth defects when taken during pregnancy. Do NOT use SOHONOS® if you are pregnant, think you may be pregnant, or are planning to become pregnant. If you can become pregnant, you should only take SOHONOS® if ALL the conditions described on page 10 or in the SOHONOS® Patient Medication Information leaflet (under the **“SOHONOS® Pregnancy Prevention Plan”**) are met.

Other warnings you should know about

SOHONOS® can cause:

- Sensitivity to sunlight and ultraviolet light and skin effects (e.g., dry skin, loss of hair, itching, rashes). To reduce these side effects, your prescribing doctor may recommend the use of:
 - Skin moisturizers, sunscreen with a broad-spectrum SPF value of 15 or higher, lip moisturizers, or other helpful treatments.
 - Protective clothing and sunglasses to help reduce exposure to sunlight.
- Dry eyes. Your prescribing doctor may recommend use of artificial tears (drops to lubricate the eye).

Driving and using machines:

- SOHONOS® may affect your ability to see in the dark. Before you drive or do tasks that require special attention, wait until you know how you respond to SOHONOS®.

Fertility:

- It is not known if SOHONOS® affects your ability to have children. Talk to your prescribing doctor if this is a concern for you.

Checkups and testing:

- You will have regular visits with your prescribing doctor during treatment with SOHONOS® and they will check for: problems with normal bone growth (in growing children) every 3 months (or as determined by your prescribing doctor); signs and symptoms of mental health problems (such as depression, anxiety, mood alterations, suicidal thoughts, and behaviours); and signs of fractures of the spine (using regular bone imaging scans). If you can become pregnant your prescribing doctor will follow up on monthly pregnancy testing.

What you need to know about SOHONOS® if you are a patient who can get pregnant

SOHONOS® must not be used by patients who are, may be, or intend to become pregnant. SOHONOS® can seriously harm an unborn baby. It can cause serious defects to the unborn baby's brain, face, ears, eyes, heart, and certain glands (thymus gland and parathyroid gland). It also makes a miscarriage more likely. This may happen even if SOHONOS® is taken only for a short time during pregnancy.

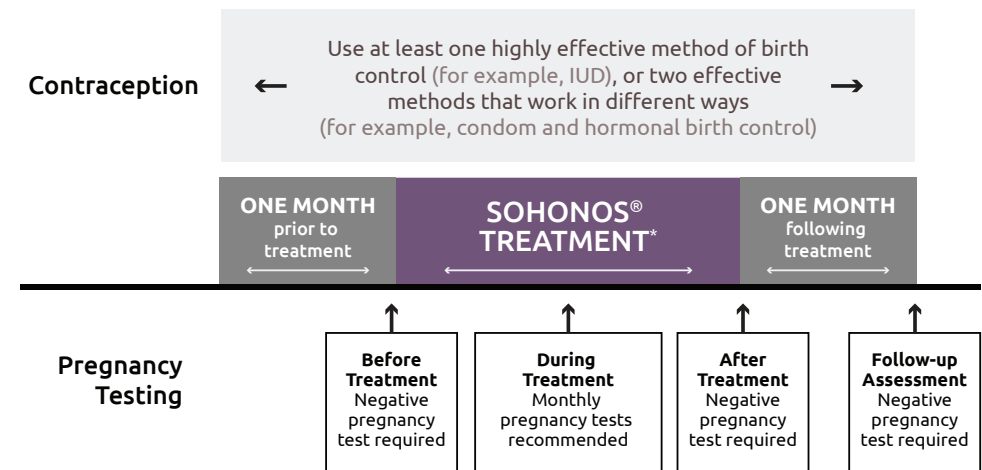
You must read and understand the information below. You and your prescribing doctor must talk about all the conditions for pregnancy prevention before being treated with SOHONOS®.

If you are a patient who can get pregnant:

- You must follow the strict rules of the **"SOHONOS® Pregnancy Prevention Plan"** outlined in the SOHONOS® Patient Medication Information leaflet.
 - You must not take SOHONOS® if you are pregnant or breastfeeding.
 - If you could get pregnant, you and your prescribing doctor must discuss the strict rules to follow before, during, and after taking SOHONOS®.
 - You must avoid getting pregnant by using effective birth control before, during, and after taking SOHONOS®.
 - You must use at least one highly effective method of birth control (for example, an intrauterine device), or two effective methods that work in different ways (for example, a hormonal birth control pill and a condom).
 - If you have any questions about acceptable birth control options while you are being treated with SOHONOS®, please ask your prescribing doctor.
 - You must have pregnancy testing before, during, and after taking SOHONOS®.
 - If you become pregnant while taking SOHONOS® or within one month after stopping treatment, you must contact your prescribing doctor right away.

- If your pretreatment counselling did not include an in-depth conversation about the **"SOHONOS® Pregnancy Prevention Plan"**, please contact your prescribing doctor.

SOHONOS® Pregnancy Prevention Plan



Adapted from the Product Monograph.

*Applies whether you are taking the SOHONOS® chronic or flare-up treatment regimen. If you are taking SOHONOS® only to treat flare-ups, you must continue to use effective birth control even during times when you are not taking SOHONOS®. This is because the timing of your flare-ups may not be predictable.

What are possible side effects from taking SOHONOS®?

These are not all the possible side effects you may have when taking SOHONOS®.

Side effects you may experience include:

- Dry skin
- Hair loss
- Itching
- Skin shedding
- Rash
- Hives
- Eczema
- Skin growth
- Nosebleed
- Headache
- Dry and scaly lips
- Dry mouth
- Lip inflammation (cheilitis)
- Nausea
- Diarrhea
- Acid reflux disease
- Infection of the nail
- Joint pain
- Back pain
- Dry eye
- Sensitivity to sunlight

If you experience side effects not listed here, tell your prescribing doctor.

What are possible serious side effects from taking SOHONOS®?

Talk to your prescribing doctor if you experience the very common serious side effect of radiological vertebral fractures (fractures of the spine as seen on an x-ray).

Talk to your prescribing doctor if you experience any of these common serious side effects:

- **Any change in mental health problems, including symptoms of depression or psychosis (a severe mental disturbance):** changes in your mood such as becoming depressed, feeling sad, or having crying spells, losing interest in your usual activities, changes in your normal sleep patterns, becoming more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence), losing your appetite, becoming unusually tired, having trouble concentrating, withdrawing from family and friends, or having thoughts about taking your own life (suicidal thoughts).
- **Bone/growth changes such as premature closure of the growth plate (in growing children):** slowing or stopping of growth which may affect height, differences in leg length, which may affect walking.
- Fatigue, loss of energy or weakness, looking pale, or shortness of breath, which could be symptoms of **anemia**.
- Pain, tenderness, swelling, or redness of the skin, which could be symptoms of cellulitis (**skin infection**).
- Itchy, red eyes with discharge, swelling, which could be symptoms of conjunctivitis (**eye infection**).

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your prescribing doctor.

Who should not use SOHONOS®?

SOHONOS® should not be used if:

- You are pregnant or breastfeeding. Physicians and patients can report pregnancies by calling 1-855-215-2288.
- There is a chance you could become pregnant. You must follow the precautions under the **“SOHONOS® Pregnancy Prevention Plan”**.
- You are allergic to palovarotene or any of the other ingredients of SOHONOS®.
- You are allergic to other retinoids.

How should I report side effects?

You can report any suspected side effects associated with the use of health products to Health Canada by:


- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Contact your prescribing doctor if you need information about how to manage side effects. The Canada Vigilance Program does not provide medical advice.

Notes

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Remember to discuss any symptoms or changes to your weight with your prescribing doctor or nurse.



For more information, refer to the Patient Medication Information leaflet that came with your SOHONOS[®] prescription or contact your healthcare team.

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