

**For more information, view the full
Product Monograph at**
health-products.canada.ca/dpd-bdpp/

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SOH/04/22/07E



Understanding the SOHONOS[®] Educational Program:

**A Guide for Patients
and their Caregivers**

**For complete safety information about SOHONOS[®],
please refer to the SOHONOS[®] package insert provided
with your medicine.**



What is SOHONOS® used for?

SOHONOS® is used to reduce the formation of heterotopic ossification. This is a condition where bone forms in soft tissues outside the skeleton. It is used in adults and children (females 8 years and older, males 10 years and older) who have the genetic disorder fibrodysplasia ossificans progressiva, also called FOP.

What are the serious risks of SOHONOS®?

- SOHONOS® can seriously harm an unborn baby. Do NOT use SOHONOS® if you are pregnant, think you may be pregnant or are planning to become pregnant. If you are of childbearing potential, you should only take SOHONOS® if ALL the conditions described in the SOHONOS® Product Monograph under **“SOHONOS® Pregnancy Prevention Plan”** are met.
- 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 doctor will explain the risks to the patient or caregiver and child. Children who are actively growing should be closely monitored (every 3 months or as determined by your doctor) during treatment with SOHONOS®.
- SOHONOS® may cause fractures of the spine (radiologically observed vertebral fractures), as seen on radiology images of some people treated with SOHONOS®.
- There are other warnings, precautions and side effects associated with taking SOHONOS®. Please read the SOHONOS® package insert that comes with your medication.

Ipsen Medical Information

To request Medical Information, report an Adverse Event or Product Quality Complaint for Ipsen Canada's products, please contact Ipsen Canada Medical Information at:
Phone: 1-855-215-2288 (Option 3)
Email: MedInfoandSafetyCanada@Ipsen.com

If you agree, your doctor can also enroll you in the SOHONOS® registry by calling the same number (1-855-215-2288, Option 3).

What is the SOHONOS® Educational Program?

The SOHONOS® Educational Program is a program to educate prescribers, pharmacists, patients, and their caregivers about the serious risks related to SOHONOS®.

What do I need to know about SOHONOS®?

Before receiving SOHONOS®, you must do the following:

1. Confirm with your doctor that SOHONOS® is appropriate for you.
2. Read all the patient information about SOHONOS®:
 - SOHONOS® package insert
 - Understanding the SOHONOS® Educational Program: A Guide for Patients Who Can Get Pregnant. The Importance of Avoiding Pregnancy for Patients Taking SOHONOS®.
 - Understanding the SOHONOS® Educational Program: A Guide for Caregivers of Growing Pediatric Patients
3. Understand what you need to do when taking SOHONOS®. Ask your doctor about anything you do not understand. These requirements include:
 - **For patients who can get pregnant:** pregnancy tests (before, during and after treatment) and use of appropriate birth control
 - **For growing children:** regular clinical monitoring every 3 months or as determined by your doctor
 - **For all patients:** regular bone imaging scans to check for signs of fractures of the spine.

How will I obtain SOHONOS®?

SOHONOS® will be prescribed to you or your child by your doctor or your child's doctor. If you have questions or concerns about SOHONOS®, talk to your doctor.