



Understanding the SOHONOS[®] Educational Program:

A Guide for Patients Who Can Get Pregnant

The Importance of Avoiding Pregnancy
for Patients Taking SOHONOS[®]

**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 you (i.e. 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®.
- Radiological vertebral fractures (spinal fractures) were identified as a risk associated 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.

This brochure focuses on the risks that affect patients who can become pregnant and how these risks must be managed when taking SOHONOS®.

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 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 on pages 5 and 6. You and your doctor must talk about all the conditions for pregnancy prevention before being treated with SOHONOS®.

SOHONOS® Pregnancy Prevention Plan

Patients who can become pregnant must meet ALL of the conditions below to use SOHONOS®.

1. You must NOT take SOHONOS® if you are pregnant, or breastfeeding.

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You must NOT

- take SOHONOS® if you are pregnant or if you think you might be pregnant.
- take SOHONOS® if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- take SOHONOS® if you could get pregnant during treatment.
- get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

2. If you could get pregnant, you and your doctor must discuss the strict rules to follow before, during and after taking SOHONOS®.

- Your doctor must explain the risk of harm to the unborn baby. You must understand why you must not get pregnant and what you need to do to prevent pregnancy.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how to avoid getting pregnant. Your doctor may send you to a specialist for birth control advice.
- You must have talked about pregnancy testing with your doctor. You must understand and agree to have regular pregnancy testing.
- Your doctor must explain to you what to do if you become pregnant, or think you might be pregnant.
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3. You must avoid getting pregnant by using effective birth control before, during and after taking SOHONOS®.

- You must be able and willing to comply with the mandatory birth control measures. Discuss with your doctor which methods would be suitable for you.
- You must use birth control even if you are not sexually active (unless your doctor decides this is not necessary).
- You must use birth control for a month before taking SOHONOS®, during treatment and for a month afterwards.
- 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 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.

SOHONOS® Pregnancy Prevention Plan

4. You must have pregnancy testing before, during and after taking SOHONOS®.

- Before you start treatment, you must take a pregnancy test. The test must show that you are not pregnant when starting treatment with SOHONOS®.
- You must have regular pregnancy tests during treatment with SOHONOS®. It is recommended that you take a pregnancy test on a monthly basis, unless otherwise advised by your doctor. Your doctor may also ask you to take a pregnancy test 1 month after stopping SOHONOS® because some medicine may still be left in your body.

5. If you become pregnant while taking SOHONOS® or within one month after stopping treatment, you must contact your doctor right away.

- If you are still taking SOHONOS®, you must stop treatment and tell your doctor right away.
- You and your doctor must discuss:
 - If you want to continue with your pregnancy
 - The serious risk of your baby having severe birth defects
- You or your doctor should report the pregnancy by calling 1-855-215-2288. If you agree, your doctor can also enroll you in the SOHONOS® registry by calling the same number (1-855-215-2288, Option 3). Educational materials can be found at www.ipsen.com/canadaen/SOEDUMAT.

If your pre-treatment counselling did not include an in-depth conversation about the SOHONOS® Pregnancy Prevention Plan, please contact your doctor.

How will I obtain SOHONOS®?

SOHONOS® will be prescribed by your doctor

If you have questions or concerns about SOHONOS®, talk to your doctor.

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) or through the SOHONOS® website.

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

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