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Understanding the SOHONOS[®] Educational Program:

A Guide for Caregivers of Growing Pediatric Patients

This brochure focuses on the risk that affects growing children and how these risks must be managed when taking SOHONOS[®].

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**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 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® 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.
- 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.

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®.

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).

About bone growth and growth plate closure

Young children and adolescents who are still growing have open growth plates. Growth plates are the area of growing tissue near the ends of the long bones of the arms and legs of children and adolescents where growth occurs until the growth plates close. The term “growth plate closure” refers to the point at which the growth plates no longer have the ability to increase the length of the bone. This typically occurs gradually over childhood, with full closure occurring near the end of puberty. This is also known as skeletal maturity.

About SOHONOS® and premature growth plate closure

SOHONOS® can cause the growth plates to close prematurely, which is known as “premature physal closure.” For this reason, it is recommended that growing children being treated with SOHONOS® who have not reached skeletal maturity or final adult height are monitored closely by their doctor, including but not limited to, an assessment of skeletal maturity via hand/wrist and knee X-rays, standard growth curves and pubertal staging prior to starting treatment with SOHONOS®. Continued monitoring of bone growth and skeletal maturity via X-ray is recommended every 3 months until skeletal maturity or final adult height (frequency of monitoring will be determined by your physician, and may depend on patient characteristics such as age, pubertal status and skeletal maturity). Once growth plates have all closed (indicating skeletal maturity), or final adult height has been reached, no further monitoring of premature physal closure is necessary.

Should evidence of adverse effects on growth and/or premature physal closure be observed, further evaluation and increased monitoring may be required. The decision to temporarily interrupt SOHONOS® during the evaluation period or permanently discontinue treatment should be made based on the individual benefit-risk determination.

How will my child receive SOHONOS®?

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