Information for Vermont Prescribers of Prescription Drugs (Long Form)

SOHONOS™ (palovarotene) Capsules

33 V.S.A. § 2005a

Please see Important Safety Information below and accompanying full Prescribing Information, including BOXED WARNING on Embryo-fetal Toxicity and Premature Epiphyseal Closure in Growing Pediatric Patients.

- This list does not imply that the products on this chart are interchangeable or have the same efficacy or safety.
- The prices listed below are Average Wholesale Prices ("AWP") as established and made available to the public by a third party publisher or as calculated from data made available to the public by a third party publisher. The price paid by consumers may be higher or lower than the prices listed below. Information about AWP of these drugs is being provided to Vermont prescribers pursuant to Vermont law, to give you information about the relative prices of marketed drugs and other drugs in the same therapeutic class.
- The prices listed here do not necessarily reflect price per dosage, price per course of treatment or the cost effectiveness, of all the products listed. For simplicity, only the smallest package sizes available for each product are included.

Product Name	Manufacturer	NDC or UPC	Package Size	AWP	
				Pack	Capsule
Marketed Products					
SOHONOS 1 mg Capsule	IPSEN Biopharmaceuticals	15054-0010-1	14 capsules	$ 5,745.60	$ 410.40
SOHONOS 1.5 mg Capsule	IPSEN Biopharmaceuticals	15054-0015-1	14 capsules	$ 8,618.40	$ 615.60
SOHONOS 2.5 mg Capsule	IPSEN Biopharmaceuticals	15054-0025-1	14 capsules	$ 14,364.00	$ 1,026.00
SOHONOS 5 mg Capsule	IPSEN Biopharmaceuticals	15054-0050-1	14 capsules	$ 28,728.00	$ 2,052.00
SOHONOS 10 mg Capsule	IPSEN Biopharmaceuticals	15054-0100-1	14 capsules	$ 57,456.00	$4,104.00
Other Products					

INDICATION

SOHONOS™ is indicated for the reduction in volume of new heterotopic ossification in adults and pediatric patients aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP).

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY and PREMATURE EPIPHYSEAL CLOSURE IN GROWING PEDIATRIC PATIENTS

- **SOHONOS is contraindicated in pregnancy. SOHONOS may cause fetal harm. Because of the risk of teratogenicity and to minimize fetal exposure, SOHONOS is to be administered only if conditions for pregnancy prevention are met.**
- **Premature epiphyseal closure occurs in growing pediatric patients treated with SOHONOS, close monitoring is recommended.**

Please see additional Important Safety Information below and accompanying full Prescribing Information, including BOXED WARNING.

IMPORTANT SAFETY INFORMATION (Continued)

Contraindications

SOHONOS is contraindicated in patients during pregnancy, or with a history of allergy or hypersensitivity to retinoids, or to any component of SOHONOS.

Warnings and Precautions

- **Embryo-Fetal Toxicity:** SOHONOS can cause fetal harm and is contraindicated during pregnancy. Advise females of reproductive potential to use an effective method of contraception at least 1 month prior to treatment, during treatment with SOHONOS and for 1 month after the last dose. If a pregnancy occurs during SOHONOS treatment, discontinue treatment immediately and refer the patient to an obstetrician/gynecologist experienced in reproductive toxicity.
  Patients should be informed not to donate blood during SOHONOS therapy and for 1 week following discontinuation.
- **Premature Epiphyseal Closure in Growing Pediatric Patients**: SOHONOS can cause irreversible premature epiphyseal closure and potential adverse effects on growth. Prior to starting treatment with SOHONOS, all growing pediatric patients should undergo baseline assessment of skeletal maturity and continued monitoring until patients reach skeletal maturity or final adult height. If appropriate, temporary or permanent discontinuation may be warranted.
- **Mucocutaneous Adverse Reactions:** Dry skin, lip dry, pruritus, rash, alopecia, erythema, skin exfoliation (skin peeling), and dry eye occurred with SOHONOS. Prophylactic measures to minimize risk and/or treat the mucocutaneous adverse reactions are recommended (e.g., skin emollients, sunscreen, lip moisturizers, or artificial tears). Some may require dose reduction or discontinuation. Photosensitivity reactions have been associated with the use of retinoids and may occur with SOHONOS. Precautionary measures for phototoxicity are recommended (use of sunscreens, protective clothing, and use of sunglasses).
- **Metabolic Bone Disorders:** Increased risk of radiologically observed vertebral fractures and decreased vertebral bone mineral content and bone density. Periodic radiological assessment of the spine is recommended. Retinoids have been associated with hyperostotic changes (bone spurs) and calcification of tendons or ligaments may occur with SOHONOS.
- **Psychiatric Disorders:** New or worsening psychiatric events were reported with SOHONOS including depression, anxiety, mood alterations, and suicidal thoughts and behaviors. Monitor for development of new or worsening psychiatric symptoms during treatment with SOHONOS. Patients and/or caregivers should contact their healthcare provider if new or worsening psychiatric symptoms develop during treatment with SOHONOS.
- **Night Blindness:** This may be dose-dependent, making driving a vehicle at night potentially hazardous during treatment. Advise patients to be cautious when driving or operating any vehicle at night and seek medical attention in the event of vision impairment.

Adverse Reactions

The most common adverse reactions (≥ 10%) are dry skin, lip dry, arthralgia, pruritus, pain in extremity, rash, alopecia, erythema, headache, back pain, skin exfoliation (skin peeling), nausea, musculoskeletal pain, myalgia, dry eye, hypersensitivity, peripheral edema, and fatigue.

Please see additional Important Safety Information below and accompanying full Prescribing Information, including BOXED WARNING.

IMPORTANT SAFETY INFORMATION (Continued)

Drug Interactions

- CYP3A4 inhibitors may increase SOHONOS exposure. Avoid concomitant use of strong or moderate CYP3A4 inhibitors, as well as grapefruit, pomelo or juices containing these fruits.
- CYP3A4 inducers may decrease SOHONOS exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers.
- The use of both vitamin A and SOHONOS at the same time may lead to additive effects. Concomitant administration of vitamin A in doses higher than the recommended daily allowance and/or other oral retinoids must be avoided due to risk of hypervitaminosis A.
- Systemic retinoid use has been associated with cases of benign intracranial hypertension (pseudotumor cerebri), some of which involved the concomitant use of tetracyclines. Avoid coadministration of SOHONOS with tetracycline derivatives.

Use in Specific Populations

- **Pregnancy:** SOHONOS is contraindicated during pregnancy. Obtain a negative serum pregnancy test within 1 week prior to SOHONOS therapy and periodically, as needed, over the course of treatment with SOHONOS and 1 month after treatment discontinuation unless patient is not at risk of pregnancy. If pregnancy occurs during treatment with SOHONOS, stop treatment immediately and refer the patient to an obstetrician/gynecologist or other specialist experienced in reproductive toxicity for evaluation and advice.
- **Lactation:** Advise females that breastfeeding is not recommended during treatment with SOHONOS, and for at least 1 month after the last dose.
- **Females and Males of Reproductive Potential:** Advise females of reproductive potential to use effective contraception at least 1 month prior to and during treatment, and for 1 month after the last dose unless continuous abstinence is chosen.
- **Pediatric Use:** All growing pediatric patients should undergo baseline assessment of growth and skeletal maturity before starting treatment and continued clinical and radiographic monitoring every 6-12 months until patients reach skeletal maturity or final adult height.
- **Renal or Hepatic Impairment:** Use of SOHONOS in patients with severe renal impairment, or with moderate or severe hepatic impairment is not recommended.

Please see accompanying full Prescribing Information, including BOXED WARNING.

For more product information please visit SOHONOS.com.

Source: AnalySource® as of 8/30/2023.

For more information about First Databank's Drug Pricing Policy, visit http://www.fdbhealth.com/policies/drug-pricing-policy/