IPSENCARES®
Coverage, Access, Reimbursement & Education Support

sohonos™
(palovarotene) capsules
1 mg | 1.5 mg | 2.5 mg | 5 mg | 10 mg

QUESTIONS? CALL IPSEN CARES AT 1-866-435-5677

HOW TO ENROLL IN THE IPSEN CARES® PATIENT SUPPORT PROGRAM

IPSEN CARES serves as a central point of contact between patients/caregivers, healthcare providers, insurance companies, and specialty pharmacies.

Instructions for Patients

- You need to complete **Steps 1, 2, 3, 4,*** and read **Step 9** outlined in **purple** on the Enrollment Form.
- Your healthcare provider will complete the steps outlined in **green**.
- It's important to fill out all sections completely to prevent enrollment delays.

☐ Fill out the **Patient Information** section in **Step 1**.

☐ Fill out the **Insurance Information** section in **Step 2**.

☐ Fill out the **IPSEN CARES Copay Program** section in **Step 3** if requesting copay assistance.

☐ Fill out the **Patient Assistance Program (PAP)** section in **Step 4** if requesting PAP.

☐ Sign the **PATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT INFORMATION** box under **Step 3** after you read the information in **Step 9**.

Your healthcare provider will complete the remainder of the form and fax the appropriate pages to IPSEN CARES.

Instructions for Prescribers

☐ Fill out the **Prescriber Information** sections in **Steps 5-8.**

☐ Sign and date the **PRESCRIBER ATTESTATION** at the end of **Step 8**.

☐ Fax the completed form to 1-855-465-3820. IPSEN CARES must receive pages 2-7 in order for the Enrollment Form to be complete. Note, Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

Once a completed Enrollment Form is received, an IPSEN CARES Patient Access Manager will perform a benefits verification and review the patient's coverage and out-of-pocket responsibility with both the prescriber and the patient, typically within 1 business day. To learn more about IPSEN CARES and support offerings, please call 1-866-435-5677, Monday – Friday, 8:00 AM – 8:00 PM ET or visit IPSENCARES.com.

*Required for patients seeking to participate in the Patient Assistance Program.

Please see accompanying full Prescribing Information, including BOXED WARNING.

IPSEN CARES® ENROLLMENT FORM

Questions? Call IPSEN CARES at 1-866-435-5677

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820

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Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

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Completed by the patient/legal guardian

STEP 1

PATIENT INFORMATION

Patient Name (First & Last) _____

Address _____

City _____

State _____ Zip _____

Date of Birth (MM/DD/YY) ____ / ____ / ____

Gender Assigned at Birth ☐ Male ☐ Female

Email _____

Home Phone # _____

Cell Phone # _____

Caregiver/Legal Guardian Name (First & Last)

_____

Caregiver/Legal Guardian Phone # _____

Relationship to Patient _____

Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening

Would you like to receive text messages from Ipsen for the purposes of helping you/the patient participate in IPSEN CARES patient support programs and/or stay on therapy, as described in Step 9 on Page 7, under *Additional Product and Support Information*? I give permission to Ipsen to contact me by text message for the purposes described in Step 9 on Page 7. Carrier, text, and data rates may apply. ☐ Yes ☐ No

Would you like to receive marketing information from Ipsen as described in Step 9 on Page 7 under *Additional Product and Support Information*? I give permission to Ipsen to contact me with information via mail, email, phone, or text message, all of which may include marketing, advertisements, disease state awareness materials, and educational material about SOHONOS and programs that support patients. I understand and agree that any information I provide may be used by Ipsen to conduct data analysis and market research, and to develop new programs and resources. Automatic dialing may be used. Carrier, text, and data rates may apply. I understand that I am not required to provide this consent as a condition of purchasing any goods or services. ☐ Yes ☐ No

STEP 2

INSURANCE INFORMATION

Complete or attach front and back copy of patient's primary and secondary insurance cards for pharmacy and medical benefits.

Is Patient Insured? ☐ Yes ☐ No

Policy Holder Name _____

Primary Insurance Co. _____

Insurance Co. Phone # _____

Subscriber Policy ID # _____

Policy/Employer/Group # _____

Is Physician a Participating Provider? ☐ Participating ☐ Non-Participating

Does Patient Have Secondary Insurance? ☐ Yes ☐ No

Secondary Insurance Co. _____

Insurance Co. Phone # _____

Subscriber Policy ID # _____

Policy/Employer/Group # _____

Pharmacy Benefit Manager _____

RxBIN _____ RxPCN _____

RxGroup _____ RxID _____

STEP 3

IPSEN CARES COPAY PROGRAM (Required for patients seeking to participate in the SOHONOS Copay Assistance Program)

Eligible patients using commercial insurance can save on out-of-pocket Ipsen medication costs. Please see Patient Eligibility & Terms and Conditions.

I attest that I am not enrolled in any health insurance plan from any state or federally funded programs (including, but not limited to, Medicare or Medicaid, VA, DOD, or TRICARE) and agree to the Terms and Conditions of the Copay Program. ☐ Yes ☐ No

☐ I would like IPSEN CARES to check my eligibility for, and enroll me into, the SOHONOS Copay Assistance Program if the results of this benefit verification determine that I have commercial or private health insurance.

PATIENT AUTHORIZATION AND ADDITIONAL PRODUCT AND SUPPORT INFORMATION

I have read and understand the IPSEN CARES Patient Authorization on Page 6 (Step 9) and agree to the terms. To the extent marked Yes above in Step 1, I have read and understand the Additional Product and Support Information on Page 7 (Step 9) and agree to the terms.

Patient/Legal Guardian Signature _____ **Date** _____

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive Pages 2-7 in order for the Enrollment Form to be complete.
Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

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Completed by the patient/legal guardian

IPSEN CARES PATIENT ASSISTANCE PROGRAM APPLICATION

(Required for patients seeking to participate in the Patient Assistance Program)

The Patient Assistance Program (PAP) is designed to provide SOHONOS at no cost to eligible patients. Patients may be eligible to receive free drug if they are experiencing financial hardship and meet financial eligibility criteria, are uninsured or functionally uninsured, residents of the U.S., and received a valid prescription for an on-label use of SOHONOS as supported by information provided in the program application. Eligibility does not guarantee approval for participation in the program. Free SOHONOS provided by the PAP is intended only for the patient named in the application and must not be sold, transferred, or otherwise diverted. Patients must not seek reimbursement for the free drug provided by the PAP. The PAP provides SOHONOS product only, and does not cover the cost of previously purchased product or medical services. The PAP is not insurance. By submitting an application for the PAP, patient agrees to abide by these program terms.

STEP 4

PROOF OF INCOME*

My estimated annual household income currently is $ _____ Number of people in household _____

***IPSEN CARES will conduct a soft credit check as part of the process of confirming income and determining eligibility for the program.**

THIRD PARTY VERIFICATION AUTHORIZATION

I understand that I am providing "written instructions" under the Fair Credit Reporting Act ("FCRA") authorizing the IPSEN CARES Patient Assistance Program (the "Program"), Ipsen Biopharmaceuticals, Inc. ("Ipsen"), and its vendor, on an ongoing basis as needed for the duration of my participation in Program, under the FCRA, to obtain information from my credit profile or other information from a credit reporting agency (including, without limitation, Experian Health), for the purpose of determining financial qualifications and eligibility for programs administered by Ipsen and the Program.
I understand that I am affirmatively agreeing to these terms in order to proceed in this financial screening process. I promise that any information, including financial and insurance information that I provide, are complete and true and, unless I have indicated otherwise, I have no drug insurance coverage, which includes Medicaid, Medicare or any public or private assistance program or any other form of insurance. If my income or health coverage changes, I will call the Program at 1-866-435-5677.

Patient/Legal Guardian Signature _____ **Date** _____

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Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

Completed by the prescriber

STEP 5

PRESCRIBER INFORMATION

Prescriber Name (First & Last) _____

State License # _____

Tax ID # _____ NPI # _____

Medicaid Provider # (Required if Medicaid Patient) _____

Provider Transaction Access # (PTAN) _____

Office/Institution _____

Specialty _____

Street Address _____

City _____ State _____ Zip _____

Office Contact and Title _____

Phone # _____ Fax # _____

Email _____

Preferred Method of Contact ☐ Phone ☐ Fax ☐ Email

Best Time to Contact ☐ Morning ☐ Afternoon ☐ Evening

STEP 6

SPECIALTY PHARMACY

If you would like IPSEN CARES to triage the prescription to the SOHONOS limited specialty pharmacy network, complete the prescription information in Step 8.

Preferred Specialty Pharmacy ☐ CVS Specialty®

Was Rx Sent to a Specialty Pharmacy Already? ☐ Yes ☐ No

If Yes, Please Provide the Name of the Specialty Pharmacy _____

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.

PRESCRIBER DOSING REFERENCE SECTION

- Recommended dosage includes a chronic daily dose, which can be increased for flare-up symptoms
- For adults and pediatric patients 14 years and older:
  Recommended dosage is 5 mg once daily, with an increase in dose at the time of a flare-up to 20 mg once daily for 4 weeks, followed by 10 mg once daily for 8 weeks for a total of 12 weeks (20/10 mg flare-up treatment)
- For pediatric patients under 14 years: Weight-adjusted for daily and flare-up dosing. Recommended daily dosage range from 2.5 to 5 mg. Refer to Table 1 in Full Prescribing Information for complete pediatric dosing
- Reduce the dose in the event of adverse reactions as appropriate
- See Section 2 of the Full Prescribing Information for complete dosing instructions

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IPSEN CARES must receive Pages 2-7 in order for the Enrollment Form to be complete.
Note: Page 3 can be left blank if the patient is not seeking to participate in the Patient Assistance Program.

Completed by the prescriber

STEP 7

DIAGNOSIS

☐ Primary Diagnosis: Myositis ossificans progressiva M61.1

☐ Other diagnosis: _____ ICD-10 _____

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.

STEP 8

PRESCRIPTION AND PRESCRIBER ATTESTATION

Complete this section if you would like IPSEN CARES to triage the prescription to a specialty pharmacy or if the patient is seeking enrollment in the PAP.

PRESCRIPTION: SOHONOS™ (palovarotene)

Patient Name (First & Last) _____ Date of Birth (MM/DD/YY) ____/____/____

Gender Assigned at Birth ☐ Male ☐ Female Current Weight ____ kg Date Measured ____/____/____ Height ____ inches

CHRONIC OR ALTERNATE DOSING			
Medication	**Strength** (Select multiple, if applicable)	**Dose & Directions**	**Quantity/Refills**
☐ SOHONOS Capsules	☐ 1 mg capsule ☐ 2.5 mg capsule ☐ 10 mg capsule ☐ 1.5 mg capsule ☐ 5 mg capsule	Take _____ mg (total daily dose) by mouth daily with food	Quantity: 28-day supply Refills: 13 or _____
FLARE UP DOSING (WEEKS 1-4)			***only if necessary for patient**
Medication	**Strength** (Select multiple, if applicable)	**Dose & Directions**	**Quantity/Refills**
☐ SOHONOS Capsules	☐ 1 mg capsule ☐ 2.5 mg capsule ☐ 10 mg capsule ☐ 1.5 mg capsule ☐ 5 mg capsule	Take _____ mg (total daily dose) by mouth daily with food	Quantity: 28-day supply Refills: NONE
FLARE UP DOSING (WEEKS 5-12)			***only if necessary for patient**
Medication	**Strength** (Select multiple, if applicable)	**Dose & Directions**	**Quantity/Refills**
☐ SOHONOS Capsules	☐ 1 mg capsule ☐ 2.5 mg capsule ☐ 10 mg capsule ☐ 1.5 mg capsule ☐ 5 mg capsule	Take _____ mg (total daily dose) by mouth daily with food	Quantity: 28-day supply Refills: 1

See full Prescribing Information for complete dosing instructions

PRESCRIBER ATTESTATION

(The Prescriber must sign if this form is to be used as a prescription to be triaged to a specialty pharmacy to enroll the patient for free goods as part of the Patient Assistance Program (PAP), or to enroll a patient for free goods as part of the Temporary Patient Assistance Program (TPAP). If the request is limited to Benefit Verification or Copay Assistance Program support, the Prescriber, or an individual acting at the direction of the Prescriber and involved in the patient's care, such as an Office Practice Manager, Financial Coordinator, Financial Counselor, Patient Assistance Coordinator, Patient Navigator, Social Worker, Insurance Coordinator, Patient Coordinator, or Patient Care Advocate, may sign this form.)

By signing below, I certify that the therapy referenced in this form is medically necessary. If this form is to be used to enroll a patient in free goods as part of the PAP or Temporary PAP, I certify that the therapy referenced in this form is prescribed consistent with an FDA-approved indication. I certify that a prescription signed by a licensed prescriber is on file for the referenced therapy and that I have received the necessary authorization from the patient and/or the patient's guardian to release the information herein and medical and/or patient information relating to SOHONOS therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for SOHONOS therapy, assisting in initiating or continuing SOHONOS therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES. I authorize Ipsen and its agents or contractors to forward a prescription by fax or other delivery mode to the designated pharmacy. I understand that I must comply with applicable state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to me. I certify that any medications received by me or on my behalf from Ipsen in connection with any IPSEN CARES program will be used only for the named patient. These medications will not be offered for sale, transfer, or otherwise diverted. Additionally, no claim for reimbursement will be submitted concerning these medications, or any services provided by IPSEN CARES, to any payor, including Medicare, Medicaid, or any other federal or state health insurance program, nor will any medications be returned for credit. If the named patient does not return for therapy, product will be returned to Ipsen. I acknowledge that I have assisted the named patient in enrolling in IPSEN CARES exclusively for purposes of patient care and not in consideration for, expectation of, or actual receipt of remuneration of any sort.

Name (First & Last) _____ **Title** _____

Prescriber Signature _____ **Date** _____

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive Pages 2-7 in order for the Enrollment Form to be complete.
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STEP 9
Completed by the patient/legal guardian

PATIENT AUTHORIZATION TO USE/DISCLOSE HEALTH INFORMATION: IPSEN CARES® PROGRAM

I authorize my/the patient's doctor(s) and their staff (including those pharmacies that may receive my/the patient's prescription for SOHONOS) to disclose my/the patient's protected health information ("PHI"), including health information about insurance, prescription, care management, and medical condition to Ipsen Biopharmaceuticals, Inc., and/or its affiliates, and/or its agents or third-party vendors that have been hired to administer the Ipsen Coverage, Access, Reimbursement & Education Support (IPSEN CARES) program (collectively, "Ipsen") in order for Ipsen to (1) enroll me/the patient in IPSEN CARES; (2) establish my/the patient's benefit eligibility and potential out of pocket costs for SOHONOS; (3) communicate with my/the patient's doctors and health plans about my/the patient's treatment plan; (4) provide support services, including patient education and financial assistance for SOHONOS; (5) help get SOHONOS shipped to me/the patient or my healthcare provider; and (6) facilitate my/the patient's participation in SOHONOS patient programs as I have requested or may request, including the IPSEN CARES Patient Assistance Program (the "PAP") if applicable. I agree that, using the contact information I provide, Ipsen may contact me/the patient by phone, mail, and/or email for reasons related to the IPSEN CARES program and support services, including (1) determining if I/the patient am/is eligible for assistance and related support services, (2) leaving messages for me that disclose that I/the patient am/is on SOHONOS therapy and/or applied for IPSEN CARES support services and am/is or am not/is not eligible for assistance; (3) operating Ipsen Cares patient programs that might help me pay for or access my/the patient's medicines; and (4) confirming receipt of medications. I consent to being contacted by an IPSEN CARES program representative in order for the program to obtain further information or clarification regarding any adverse event I/the patient may experience. I also give Ipsen permission to share my/the patient's PHI and other information with people and companies that work with IPSEN CARES, including; government agencies, including insurance providers; my/the patient's doctor(s) and other people, or institutions who are involved in my/the patient's healthcare, such as pharmacies and hospitals; and/or other organizations that might help me pay for my/the patient's medication. All information that I provide may be used by Ipsen or any third party working on behalf of Ipsen in connection with IPSEN CARES. I understand that my/the patient's healthcare providers may receive remuneration from Ipsen in connection with my/the patient's PHI and/or for any therapy support services provided to me/the patient.

I understand that once my/the patient's PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws, and Ipsen may re-disclose it; however, Ipsen has agreed to make reasonable efforts to protect my/the patient's PHI by using and disclosing it only for the purposes described above or as required by law. I can withdraw this authorization by contacting IPSEN CARES at 1-866-435-5677or mailing a letter requesting such revocation to IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560, but it will not change any actions taken before I withdraw this authorization. Withdrawal of this authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon this authorization. I understand that I may refuse to sign this form and, if I do so, I/the patient will not be able to participate in IPSEN CARES, but it will not affect my/the patient's eligibility to obtain medical treatment, my/the patient's ability to seek payment for this treatment, or affect my/the patient's insurance enrollment or eligibility for insurance coverage. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I understand that I will receive a copy of the signed authorization.

I confirm that any information, including financial and insurance information, that I provide to IPSEN CARES is complete and true, and unless I have said something different in this application, I have no insurance coverage for this product, which includes Medicaid, Medicare, or any public or private assistance programs or any other form of insurance. If my income or health insurance coverage changes, I will immediately notify IPSEN CARES at 1-866-435-5677. I confirm that I/the patient am/is a resident of the United States (including its territories). I understand that Ipsen may revise, change, or terminate this program at any time without notice.

Please print the form, fill it out completely, sign it, and fax to: 1-855-465-3820
IPSEN CARES must receive Pages 2-7 in order for the Enrollment Form to be complete.
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Completed by the patient/legal guardian

STEP 9 (continued)

ADDITIONAL PRODUCT AND SUPPORT INFORMATION

Text Communications

To the extent that I have opted in under Step 1 of this form, I agree to be contacted by autodialed text messages ("texts") at the mobile phone number I have provided for the purpose of helping me/the patient stay on therapy, which may promote or advertise the Ipsen products included in the therapy plan, and/or which may include provision of educational materials and information about programs that support patients. I certify that the number I am providing belongs to me and not a family member or third party. I understand that I may opt out of individual communications or all text communications entirely at any time by calling 1-866-435-5677 or replying "STOP" by text to any text from Ipsen. Ipsen will not sell or rent this information and will use it only in accordance with this authorization and consent. Consent to being contacted by text messages is not a condition of participation in the IPSEN CARES programs or the purchase of any products or services. I understand that my cellular service carrier's data and text messaging rates may apply. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

Marketing Information

To the extent that I have opted in under Step 1 of this form, I would like to receive information from Ipsen via mail, email, phone or text message, all of which may include marketing content, advertisements, disease state awareness materials and educational material about SOHONOS, and programs that support patients. These text messages and voice calls may be made via the use of automatic telephone dialing systems. I certify that the number I am providing belongs to me and not to a family member or other third party. I understand that I do not have to sign this section of the form in order to participate in the IPSEN CARES program and that I may revoke this authorization to receive additional product information at any time. I agree that Ipsen and its agents may use and disclose my personal information (including name, address, phone number, and/or email) to provide this information and Ipsen may also contact me to solicit my opinions regarding SOHONOS and Ipsen's products and services. I understand and agree that any information I provide may be used by Ipsen to conduct data analysis and market research, and to develop new programs and resources. I understand that my cell phone carrier's standard rates may apply for calls and texts to my cell phone. This authorization expires three years from the date signed unless a shorter time is required by law or unless I revoke my authorization before that time. I may revoke this authorization, by calling 1-866-435-5677 or sending a request in writing to: IPSEN CARES, 2250 Perimeter Park Dr. Suite 300 Morrisville, NC 27560. If I am providing this consent on behalf of another person, I certify that I am authorized to agree to every element of this consent on behalf of such other person, and I agree that I will be liable and will hold Ipsen harmless in the event that such other person alleges that they did not give consent.

We are collecting personal information in order to fulfill your request. Please see Ipsen's privacy policy at https://www.ipsen.com/us/privacy-policy/. Residents of certain states have additional rights regarding the collection, use, and disclosure of their personal information. For more information, please see Ipsen's Supplemental State Privacy Notice at https://www.ipsen.com/us/Supplement-Website-Privacy-Notice/.

INDICATION and IMPORTANT SAFETY INFORMATION

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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.**

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.

Warnings and Precautions (Continued)

- **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.

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.

IPSENCARES® Coverage, Access, Reimbursement & Education Support