



sohonos[™]
(palovarotene) capsules

1 mg | 1.5 mg | 2.5 mg | 5 mg | 10 mg

HEALTH JOURNAL

Please see **Indication & Important Safety Information**,
and full **Prescribing Information**, including Medication Guide
with **IMPORTANT WARNING** on Birth Defects and Bone
Growth Changes.

TRACKING YOUR HEALTH

Your Treatment Tracker is intended to help you monitor important changes in your SOHONOS™ (palovarotene) dose, symptoms, physical health, and mental well-being. While your tracker provides preset sections, you should feel free to use this as you see fit.

Date and current dose

Note the date and your current dose at the top of each page. Daily or flare-up doses you are taking could be adjusted because of side effects you may experience. If you find your side effects to be unbearable, your doctor may recommend a reduced dose.

Flare-ups

If you are experiencing a flare-up, you can log the date and location of the flare-up on these pages. Additional pages for tracking flare-ups are located in the back of this booklet.

Symptoms and side effects

You can track the type, location, and severity of certain side effects. While the meaning of the severity scale may vary from person to person, using the scale consistently may help you track how you are feeling over time.

An open-ended section is included for additional notes about symptoms you may be experiencing.

MONTH	DAY	YEAR
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Current dose (mg)

2.5 3 4 5 6 7.5 10 12.5 15 20 OTHER _____

Flare-ups

Are you currently experiencing a flare-up? YES NO

Location(s): _____

Side Effects

Skin-Related

Symptom: DRY PAIN ITCH RED OTHER _____

Location: SKIN EYES LIPS HAIR OTHER _____

Severity: 1 2 3 4 5 6 7 8 9 10
LEAST MOST

Other symptoms: _____

Please see **Indication & Important Safety Information**, and full **Prescribing Information**, including Medication Guide with **IMPORTANT WARNING**.

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TRACKING YOUR HEALTH (continued)

Side Effects (continued)

Joint Pain

Location: _____

Severity: 1 2 3 4 5 6 7 8 9 10
LEAST MOST

Muscle Pain

Location: _____

Severity: 1 2 3 4 5 6 7 8 9 10
LEAST MOST

Other symptoms: _____

How are you feeling today?

Please see [Indication & Important Safety Information](#), and full [Prescribing Information](#), including Medication Guide with **IMPORTANT WARNING**.

Journaling section

This section is for you to fill out however you like. You can track anything from changes in your health to important events. You may choose to keep tabs on how you are feeling emotionally, not just physically.

Here are some things you may want to track:

- How is your body feeling?
- How are you sleeping?
- Have there been any changes in your menstrual cycle?
- Have you done anything fun lately?
- Are you having trouble paying attention?
- Was there a time recently that you felt angry, sad, or scared? How did you manage it?

Please see [Indication & Important Safety Information](#), and full [Prescribing Information](#), including Medication Guide with **IMPORTANT WARNING.**

INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS SOHONOS™ (palovarotene)?

SOHONOS is a prescription medicine used to reduce the amount of new heterotopic ossification in adults and children 8 years of age and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). SOHONOS is not recommended for females younger than 8 years of age or males younger than 10 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SOHONOS?

SOHONOS can cause birth defects (deformed babies) if taken during pregnancy. Females who are pregnant or who plan to become pregnant must not take SOHONOS.

- Your healthcare provider will ask you to take a pregnancy test 1 week before starting treatment with SOHONOS, periodically during treatment, and 1 month after you stop treatment.
- You must use effective birth control (contraception) starting at least 1 month before starting treatment with SOHONOS, during treatment, and for 1 month after the last dose. Talk to your healthcare provider about birth control methods that may be right for you.
- If you become pregnant or think you may be pregnant during treatment with SOHONOS, stop taking SOHONOS and call your healthcare provider right away.

Because SOHONOS can cause birth defects, SOHONOS is only for people who can understand and agree to carry out all instructions for pregnancy prevention.

SOHONOS can cause bone growth changes. Children may stop growing while taking SOHONOS. Bone growth changes such as permanent early closure of the growth plate in growing children have happened with SOHONOS. Your healthcare provider will closely monitor your child's bone growth and height during treatment with SOHONOS.

Please see Indication & Important Safety Information, and full Prescribing Information, including Medication Guide with IMPORTANT WARNING.

IMPORTANT SAFETY INFORMATION (continued)

Who should not take SOHONOS?

Do not take SOHONOS if you are pregnant, or allergic to medicines known as retinoids or any of the ingredients in SOHONOS.

What should I tell my healthcare provider before taking SOHONOS?

Before taking SOHONOS, tell your healthcare provider about all your medical conditions, including:

- have bone loss (osteoporosis), weak bones or any other bone problems
- have or had mental health problems
- have or have had kidney problems
- have or have had liver problems
- are breastfeeding or plan to breastfeed. It is not known if SOHONOS passes into your breastmilk. Breastfeeding is not recommended during treatment with SOHONOS and for at least 1 month after the last dose of SOHONOS. Talk to your healthcare provider about the best way to feed your baby if you take SOHONOS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOHONOS and certain other medicines can interact with each other, sometimes causing serious side effects. Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.

What should I avoid while taking SOHONOS?

- Do not get pregnant while taking SOHONOS.
- Avoid excessive exposure to sunlight and ultraviolet lights (tanning machines). SOHONOS may make your skin more sensitive to the exposure and you may burn more easily. Apply sunscreen and wear protective clothing and sunglasses when in sunlight.
- Avoid driving at night until you know if SOHONOS has affected your vision. SOHONOS may decrease your ability to see in the dark.
- Do not donate blood while taking SOHONOS and for 1 week after stopping SOHONOS.

Please see Indication & Important Safety Information, and full Prescribing Information, including Medication Guide with IMPORTANT WARNING.

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of SOHONOS?

SOHONOS can cause serious side effects, including:

- **skin-related events** such as dry skin, lip and eye, hair loss, itching, redness, rash, and skin peeling. You may be at increased risk of developing skin and soft tissue infections while taking SOHONOS. If you develop these symptoms, your healthcare provider may tell you to use moisturizer, sunscreen, or artificial tears.
- **bone mineral density problems** (bone thinning) which can increase the risk of fractures in adults and children. Your healthcare provider should check you for this during treatment with SOHONOS.
- **new or worsening mental health problems** that may include depression, anxiety, mood changes, and suicidal thoughts and behaviors. If you have a history of mental health problems, you may be at a higher risk of developing these side effects. Call your healthcare provider if you develop new or worsening mental health symptoms during treatment with SOHONOS. Your healthcare provider should monitor you for signs of depression and refer you for appropriate treatment, if necessary.
- **vision problems (night blindness)** which may cause difficulty seeing at night or in low lit areas. Your healthcare provider should send you to see an eye specialist if you experience vision problems.

The most common side effects of SOHONOS include:

- dry skin
- rash
- nausea
- dry lips
- skin peeling
- muscle and joint pain
- hair loss
- drug eruption
- dry eyes
- itching
- skin irritation
- headache
- redness
- swelling and small cracks in corner of the mouth
- fatigue

These are not all the possible side effects of SOHONOS. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information, including Medication Guide with IMPORTANT WARNING.



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