

SOHONOS™ (palovarotene)

Educational Program Materials for Patients and Their Caregivers

WHAT IS SOHONOS?

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 of age 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.

WHAT ARE THE SERIOUS RISKS OF 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.**

Females who can become pregnant:

- 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 with SOHONOS.
- 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 full [Prescribing Information](#), including [Medication Guide](#) with IMPORTANT WARNING on Birth Defects and Bone Growth Changes.

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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.

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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 Important Safety Information on pages 2-3 and accompanying full [Prescribing Information](#), including [Medication Guide](#) with IMPORTANT WARNING.

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IMPORTANT SAFETY INFORMATION (CONT.)

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
- dry lips
- hair loss
- itching
- redness
- rash
- skin peeling
- drug eruption
- skin irritation
- swelling and small cracks in corner of the mouth
- nausea
- muscle and joint pain
- dry eyes
- headache
- 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 on Birth Defects and Bone Growth Changes.**

Please see Important Safety Information on pages 2-3 and accompanying full [Prescribing Information](#), including [Medication Guide](#) with **IMPORTANT WARNING.**

SOHONOS™ (palovarotene)

Understanding the SOHONOS (palovarotene) Educational Program: A Guide for Patients and Their Caregivers

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WHAT IS THE SOHONOS EDUCATIONAL PROGRAM?

The SOHONOS Educational Program is a program to educate prescribers, pharmacists, patients and their caregivers about the important risks related to SOHONOS.

WHAT IS SOHONOS?

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Females who can become pregnant:

- 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 with SOHONOS.
- 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.

WHAT SHOULD I AVOID WHILE TAKING SOHONOS?

- Do not get pregnant while taking SOHONOS. See "**WHAT ARE THE SERIOUS RISKS OF SOHONOS**"
- Avoid excessive exposure to sunlight and ultraviolet lights (e.g., tanning machines). SOHONOS may make your skin more sensitive to sunlight and ultraviolet light and you may burn more easily. You should use sunscreen and wear sunglasses and protective clothing that covers your skin to help protect against sunburn if you must be in the sunlight during treatment with SOHONOS.
- 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.

WHAT ARE POSSIBLE SIDE EFFECTS OF SOHONOS?

- **Skin-related problems:** SOHONOS may cause skin-related problems including dry skin, lips and eyes, 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 a moisturizer, sunscreen, or artificial tears.
- **Bone mineral density problems:** SOHONOS can cause a reduction in bone mineral density (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:** SOHONOS may cause new or worsening mental health problems that include depression, anxiety, mood changes, and suicidal thoughts and behaviors. If you have a

Please see Important Safety Information on pages 2-3 and accompanying full [Prescribing Information](#), including [Medication Guide](#) with IMPORTANT WARNING.

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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:** Decreased vision in the dark (night blindness). You may have 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
- dry lips
- hair loss
- itching
- redness
- rash
- skin peeling
- drug eruption
- skin irritation
- swelling and small cracks in corner of the mouth
- nausea
- muscle and joint pain
- dry eyes
- headache
- fatigue

Please read the SOHONOS [Medication Guide](#) that comes with your medication for more details regarding the risks described above.

WHAT DO I NEED TO KNOW ABOUT SOHONOS?

Before receiving SOHONOS, you must do the following:

1. **Talk with your doctor to ensure the benefits outweigh the risks of taking SOHONOS.**
2. **Read all the patient information about SOHONOS:**
 - a. SOHONOS [Medication Guide](#)
 - b. **Female Patients:** Understanding the SOHONOS Educational Program: A Guide for Females. The Importance of Avoiding Pregnancy for Female Patients Taking SOHONOS.
 - c. **Caregivers of Pediatric Patients:** Understanding the SOHONOS Educational Program: A Guide for Caregivers of Growing Pediatric Patients
 - d. All SOHONOS Education materials can be obtained at www.SOHONOS.com.
3. **Understand what you need to do when taking SOHONOS. Ask your doctor about anything you do not understand. These requirements include:**
 - a. **For females who can get pregnant:** pregnancy tests and use of appropriate birth control
 - b. **For growing children:** regular clinical monitoring

You are encouraged to talk with your healthcare provider about any concerns or questions you may have.

HOW WILL I OBTAIN MY SOHONOS?

Your prescription will be sent to a specialty pharmacy that will ship the medication to your home.

If you have questions or concerns about SOHONOS, talk to your doctor. Please visit www.SOHONOS.com or call +1-855-463-5127 for more information about the SOHONOS Educational Program.

Please see full [Prescribing Information](#), including [Medication Guide](#) with IMPORTANT WARNING on Birth Defects and Bone Growth Changes.

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SOHONOS™ (palovarotene)

Understanding the SOHONOS (palovarotene) Education Program: A Guide for Females

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

The health information contained within this guide is provided for general educational purposes only. Your healthcare professional is the best source of information regarding your health. Please consult your healthcare professional if you have any questions about your health or treatment.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **IMPORTANT WARNING on Birth Defects and Bone Growth Changes**.

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WHAT IS THE SOHONOS EDUCATIONAL PROGRAM?

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WHAT IS SOHONOS?

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WHAT ARE THE SERIOUS RISKS OF 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.**

Females who can become pregnant:

- 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 with SOHONOS.
- 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.

WHAT SHOULD I AVOID WHILE TAKING SOHONOS?

- Do not get pregnant while taking SOHONOS. See "**WHAT ARE THE SERIOUS RISKS OF SOHONOS**"
- Avoid excessive exposure to sunlight and ultraviolet lights (e.g., tanning machines). SOHONOS may make your skin more sensitive to sunlight and ultraviolet light and you may burn more easily. You should use sunscreen and wear sunglasses and protective clothing that covers your skin to help protect against sunburn if you must be in the sunlight during treatment with SOHONOS.
- 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.

WHAT ARE POSSIBLE SIDE EFFECTS OF SOHONOS?

- **Skin-related problems:** SOHONOS may cause skin-related problems including dry skin, lips and eyes, 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 a moisturizer, sunscreen, or artificial tears.
- **Bone mineral density problems:** SOHONOS can cause a reduction in bone mineral density (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:** SOHONOS may cause new or worsening mental health problems that include depression, anxiety, mood changes, and suicidal thoughts and behaviors. If you have a

Please see Important Safety Information on pages 2-3 and accompanying full [Prescribing Information](#), including [Medication Guide](#) with IMPORTANT WARNING.

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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:** Decreased vision in the dark (night blindness). You may have 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
- dry lips
- hair loss
- itching
- redness
- rash
- skin peeling
- drug eruption
- skin irritation
- swelling and small cracks in corner of the mouth
- nausea
- muscle and joint pain
- dry eyes
- headache
- fatigue

Please read the SOHONOS [Medication Guide](#) that comes with your medication for more details regarding the risks described above.

WHAT TO KNOW ABOUT SOHONOS IF YOU ARE FEMALE

SOHONOS must not be used by female patients who are or may become pregnant. There is a high risk that severe birth defects will result if pregnancy occurs while taking SOHONOS in any amount, even for short periods of time.

Your doctor will obtain a blood sample prior to SOHONOS treatment to determine if you are pregnant. Pregnancy testing will be done by your doctor periodically over the course of treatment with SOHONOS and one month after treatment discontinuation unless you are not at risk of becoming pregnant.

You must read and understand the information below. You and your doctor must talk about the steps to take to be treated with SOHONOS safely.

If you are a female who can get pregnant:

- Your doctor will explain the risk of harm to the unborn baby so you must understand why you must not get pregnant and what you need to do to prevent pregnancy.
- Your doctor will request that you do pregnancy tests before initiating treatment, periodically during treatment and one month after stopping your SOHONOS treatment.
- You must remain *abstinent* from heterosexual sex during treatment and for 1 month after treatment.

-or-

- You must use at least one *highly effective method of birth control* (such as an IUD) or *two effective methods* (such as combined hormonal contraception in combination with another method of contraception such as a barrier method) for at least 1 month before you start treatment with SOHONOS and continue using these methods of birth control during treatment and for 1 month after treatment if you are having heterosexual sex.

Abstinence from heterosexual sex is only acceptable as “true abstinence.” True abstinence occurs when it is in

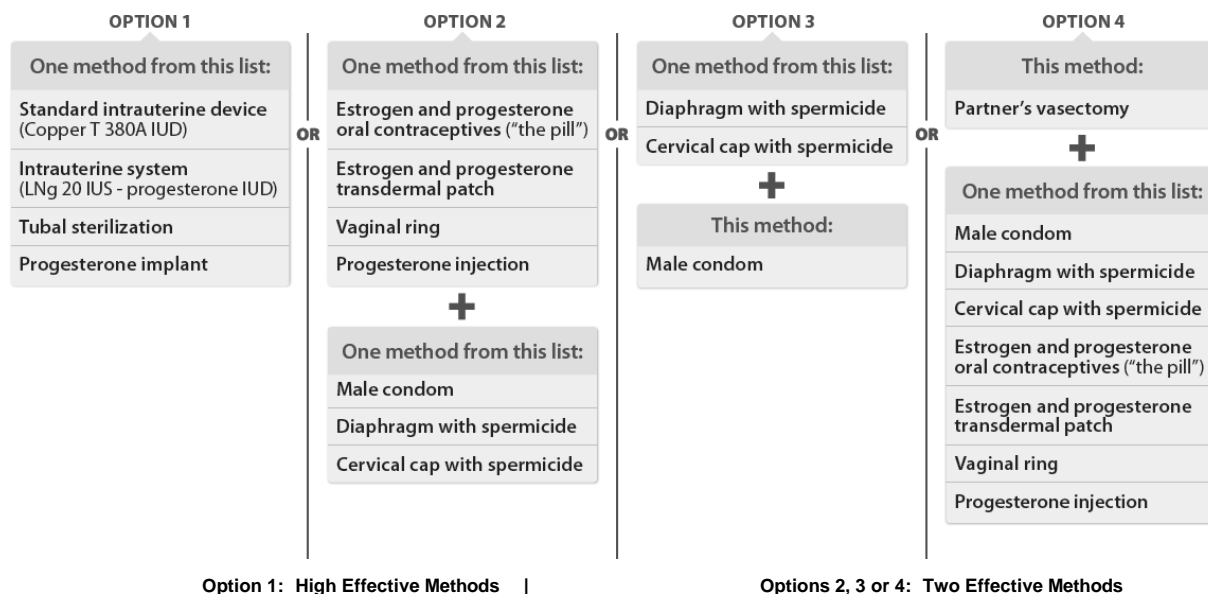
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line with your preferred and usual lifestyle. Periodic abstinence from heterosexual sex (such as calendar, ovulation, symptothermal, post-ovulation methods), the rhythm method, and withdrawal are not acceptable methods of contraception.

Refer to the table below for further details on birth control options.

Your Birth Control Options



The following are **unacceptable** forms of birth control:

- Progestin-only "mini-pill"
- Female condom
- Natural family planning (periodic abstinence, such as calendar, ovulation, symptothermal, post-ovulation methods; rhythm method; or breastfeeding) or withdrawal

If you are female and become pregnant during your treatment or in the month after stopping the treatment, you must notify your doctor immediately.

If you have any questions about acceptable birth control options while treated with SOHONOS, please ask your healthcare provider. You are encouraged to talk with your healthcare provider about any concerns or questions you may have.

HOW WILL I OBTAIN MY SOHONOS?

Your prescription will be sent to a specialty pharmacy that will ship the medication to your home.

If you have questions or concerns about SOHONOS, talk to your doctor. Please visit www.SOHONOS.com or call +1-855-463-5127 for more information about the SOHONOS Educational Program.

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SOHONOS™ (palovarotene)

Understanding the SOHONOS (palovarotene) 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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WHAT ARE POSSIBLE SIDE EFFECTS OF SOHONOS?

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The most common side effects of SOHONOS include:

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

Please read the SOHONOS [Medication Guide](#) that comes with your medication for more details regarding the risks described above.

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 in 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. For this reason, your child’s healthcare provider will closely monitor your child’s bone growth and height during treatment. Continued monitoring is recommended every 6-12 months until patients reach skeletal maturity or final adult height. Once the patient’s growth plates have all closed, indicating skeletal maturity or the patient has reached the final adult height, no further monitoring is necessary.

Should evidence of adverse effects on growth and/or premature epiphyseal 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. You are encouraged to talk with your healthcare provider about any concerns or questions you may have.

HOW WILL MY CHILD RECEIVE SOHONOS?

Your child’s prescription will be sent to a specialty pharmacy that will ship the medication to your home.

If you have questions or concerns about SOHONOS, talk to your doctor. Please visit www.SOHONOS.com or call +1-855-463-5127 for more information about the SOHONOS Educational Program.

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