SOHONOS®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before taking this medicine.

1. Why am I taking SOHONOS?

SOHONOS contains the active ingredient palovarotene. SOHONOS is used for reducing inappropriate bone formation in muscle and soft tissues in adults and children (aged 8 years and above for females and 10 years and above for males) with fibrodysplasia ossificans progressiva (FOP). For more information, see Section 1. Why am I taking SOHONOS? in the full CMI.

2. What should I know before I take SOHONOS?

Do not use if you have ever had an allergic reaction to palovarotene or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take SOHONOS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOHONOS and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take SOHONOS?

- The recommended dosage regimen of SOHONOS consists of a combination of daily treatment referred to as ‘Chronic Treatment’ and a higher-dose treatment taken at the time of a flare-up known as ‘Flare-up Treatment’.
- Chronic Treatment: The recommended dose for adults and children over 14 years of age is 5 mg once daily.

- Flare-up Treatment: **On starting Flare-up dosing you must stop Chronic daily dosing.** The recommended dose is 20 mg once daily for the first 4 weeks, followed by 10 mg once daily for 8 weeks for a total of 12 weeks even if symptoms resolve earlier.
- For children under 14 years of age your doctor will adjust the dose based on the weight of the child for both chronic and flare-up treatment. More instructions can be found in Section 4. How do I take SOHONOS? in the full CMI.

5. What should I know while taking SOHONOS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking SOHONOS. • Use effective contraception before, during and after taking SOHONOS (for women, unless your doctor

	decides this is not necessary) because SOHONOS can seriously harm an unborn baby. • Ensure women who are pregnant or who intend to become pregnant avoid contact with SOHONOS.	
Things you should not do	• You should not donate blood during treatment with this medicine and for 1 month after stopping SOHONOS because	

	an unborn baby could be harmed if a pregnant patient receives your blood. • You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment. • Avoid taking grapefruit juice or grapefruit-containing products while taking SOHONOS.

Driving or using machines	• SOHONOS may have a minor influence on the ability to drive and use machines and may affect your ability to see in the dark. SOHONOS should be taken with caution.
Looking after your medicine	• Keep blister strip in the outer carton in order to protect from light. • Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while taking SOHONOS? in the full CMI.

6. Are there any side effects?

The most common side effects are infection of the nail, headache, dry eyes, nose bleeds, dry lips and mouth, nausea, dry skin, hair loss and rashes. Serious side effects include early closure of growth plates in growing children, skin infection (cellulitis), depression linked with suicidal thoughts, seizures (fits), and fracture within the spine (vertebral fracture). For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING:

Can seriously harm an unborn baby. Women must use effective contraception.

Do not take SOHONOS if you are pregnant or you think you may be pregnant. See section 2 'What should I know before I take SOHONOS'.

Can cause bone growth to stop early in growing patients.

Close monitoring is recommended in growing patients. See section 2 'What should I know before I take SOHONOS'.

SOHONOS®

Active ingredient: *Palovarotene*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOHONOS. **You should also speak to your doctor or pharmacist if you would like further information or**

if you have any concerns or questions about using SOHONOS.

Keep this leaflet with the medicine. You may need to read it again.

Where to find information in this leaflet:

1. Why am I taking SOHONOS?
2. What should I know before I take SOHONOS?
3. What if I am taking other medicines?
4. How do I take SOHONOS?
5. What should I know while taking SOHONOS?
6. Are there any side effects?
7. Product details

1. Why am I taking SOHONOS?

SOHONOS contains the active ingredient palovarotene. SOHONOS interrupts the process where damaged soft tissues are replaced by bone. Palovarotene is a member of the retinoid class of drugs.

SOHONOS is used for preventing inappropriate bone formation in muscle and soft tissues in adults and children (aged 8 years and above for females and 10 years and above for males) with fibrodysplasia ossificans progressiva (FOP).

FOP is a disorder in which skeletal muscle and connective tissue, such a tendons and ligaments, are gradually replaced by bone.

2. What should I know before I take SOHONOS?

Warnings

Do not take SOHONOS if:

- you are allergic to palovarotene, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you are pregnant or breastfeeding.
- you are a female who is able to get pregnant you must not take this medicine unless you follow all of the conditions for pregnancy prevention. See additional information in this section under Pregnancy and breastfeeding.

You must not become pregnant while taking this medicine. You must stop taking this medicine immediately and contact your doctor if you do become pregnant or think you might be pregnant.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have liver or kidney problems. This medicine is not recommended to be taken by people with severe kidney or liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Growing Children

SOHONOS causes early closing of growth plates in growing children

A growth plate is the area of growing tissue found at the ends of bones. This medicine can cause growth plates to fuse stopping any further growth, therefore your doctor will monitor your child’s growth whilst taking this medicine.

Pregnancy and breastfeeding

Pregnancy Prevention

Women who are pregnant must not take SOHONOS.

This medicine can seriously harm an unborn baby (the medicine is said to be 'teratogenic') - it can cause serious abnormalities such as cleft palate (where the roof of the mouth does not form properly), misshapen skull (head) bones and abnormal growth of other bones (they may be too short or not symmetrical). This may happen even if this medicine is taken only for a short time during pregnancy.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You **must not take** this medicine if:

- you are pregnant or if you think you might be pregnant.
- you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- you could get pregnant during treatment.

You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed SOHONOS under strict rules. This is because of the risk of serious harm to the unborn baby.

These are the rules:

- your doctor must explain the risk of harm to the unborn baby.
- you must understand why you must not get pregnant and what you need to do to prevent pregnancy.
- you must have talked about contraception (birth control) with your doctor. Your doctor will give you information on how not to get pregnant. Your doctor may send you to a specialist for contraception advice.
- before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with this medicine. You will be required to show that you are not pregnant every month while taking this medicine and one month after stopping treatment.

Women must use effective contraception before, during and after taking SOHONOS

- you must agree to use at least one highly effective method of contraception (for example, an intra uterine device) or two effective methods that work in different ways (for example, a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- you must use contraception for a month before taking this medicine, during treatment and for a month afterwards.
- if you are taking this medicine **only** for the treatment of flare-ups (not chronic dosing), you must continue to use effective contraception even during times when you are not taking this medicine, as the timing of flare-ups may not be predictable.
- you must use contraception even if you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to be in touch with their doctor monthly to ensure they are not pregnant.

- you must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body.
- you must agree to have monthly pregnancy tests before you start treatment, during treatment and, because some medicine may still be left in your body, one month after stopping this medicine (unless your doctor decides this is not necessary for you).

- Your doctor will discuss and make sure you understand and agree to follow the rules above.

If you become pregnant while taking SOHONOS, **stop taking the medicine straight away,** and contact your doctor. Your doctor may send you to a specialist for advice.

Also, if you become pregnant within one month after you stop taking this medicine, you must contact your doctor. Your doctor may send you to a specialist for advice.

Male Patients

The amount of medicine that passes into the semen of males is too low to cause any ill effects to a female partner or her unborn child.

Bone safety

Tell your doctor if you are taking vitamin A-containing supplements while taking SOHONOS as it could increase the chances of getting these side effects.

Fractures of the spine (vertebral fracture)

This medicine may cause fractures of the spine (vertebral fractures), as seen on radiology images of some people treated with SOHONOS. Periodic radiology imaging for this risk is recommended during treatment with this medicine.

Bone spurs

This medicine may cause a build-up of calcium in bones, tendons or ligaments. This can happen with long-term use, especially at high doses.

Skin reactions

Tell your doctor or pharmacist if you experience a skin reaction that looks like severe sunburn (burning, reddening, blistering). These symptoms may appear when exposed to the sun, therefore you must avoid being out in the sun for long periods of time. You may also notice:

- dry skin
- dry lips
- dry eyes
- loss of hair
- itching, rash, redness, skin exfoliation (shedding), skin irritation, bedsores, or infection around the skin of your finger or toenails

Tell your doctor or pharmacist if you notice any of these symptoms.

Your doctor may recommend the use of skin emollients, sunscreen, lip moisturisers, artificial tears (drops to lubricate the eye), or other helpful treatments to reduce these side effects. Protective clothing and sunglasses may also help to reduce exposure to sunlight and minimise these side effects.

Mental health problems

Depression, worsening of depression, anxiety, changes in mood and suicidal thoughts and behaviours (suicide attempts) have been reported in patients treated with medicines like SOHONOS. Tell your doctor if you notice any mental health problems while taking this medicine. If you have a history of mental health problems tell your doctor as extra care must be taken while taking this medicine.

Night blindness

This medicine may cause night blindness (poor vision at night). Talk to your doctor if you experience any visual difficulties.

Other

SOHONOS and other types of 'retinoids' may cause problems with the levels of fat in your blood, liver problems, or inflammation of the pancreas.

Children and adolescents

Do not give this medicine to children under the age of 8 years (girls) and 10 years (boys).

Clinical studies of this medicine in growing children have identified a serious side effect in which bone growth can be stopped early (this is called early closure of growth plates). This effect on bone growth is permanent and can cause short stature (height) and differences

in limb length (arms and legs). Your doctor will explain the risks to you and your child. Your doctor will closely monitor you child's growth during treatment and may stop treatment if your child is affected.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with SOHONOS and affect how it works.

Medicines that may <u>increase</u> the effect of SOHONOS include:

- vitamin supplements containing vitamin A or other medicines derived from vitamin A used for skin conditions, known as 'retinoids', such as acitretin, isotretinoin, tretinoin, adapalene and tazarotene. Because Vitamin A in high doses has many of the same side effects as SOHONOS. Taking both together may increase your chance of getting side effects.
- medicines used to treat fungal infections, such as fluconazole, itraconazole and ketoconazole.
- medicines called "protease inhibitors" used to treat human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) or COVID 19 infection such as ritonavir and nirmatrelvir.

- medicines used to treat bacterial infections (antibiotics), such as clarithromycin, erythromycin and tetracyclines.
- Diltiazem which is a medicine used to treat heart conditions including angina, high blood pressure, arrythmias and heart failure.
- A medicine called aprepitant used to prevent nausea (feeling sick in your stomach) and vomiting.

Medicines that may <u>reduce</u> the effect of SOHONOS include:

- medicines used to treat epilepsy, such as phenytoin and carbamazepine.
- A medicine called bosentan used to treat pulmonary arterial hypertension (high blood pressure in the blood vessels in the lungs).
- medicines used to treat bacterial infections (antibiotics), such as rifampicin and rifabutin.
- herbal preparations containing St John's Wort extract (*Hypericum perforatum*).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOHONOS.

4. How do I take SOHONOS?

How much to take

- The recommended dosage regimen of SOHONOS consists of a combination of daily treatment referred to as ‘Chronic Treatment’ and a higher-dose treatment

taken at the time of a flare-up known as ‘Flare-up Treatment’.

- Follow the instructions provided and take SOHONOS until your doctor tells you to stop.

Chronic Treatment

- The recommended dose for adults and children 14 years of age and older is 5 mg once daily.
- For children under 14 years of age your doctor will adjust the dose based on the weight of the child.

You must stop taking the Chronic dose at the time a flare-up starts and you begin taking the Flare-up dose. Do not take both doses at the same time.

Flare-Up Treatment

On starting Flare-up dosing you must stop Chronic daily dosing.
At the time of a flare-up or a trauma that could lead to a flare-up the dose is increased to 20 mg once daily for the first 4 weeks, followed by 10 mg once daily for 8 weeks, for a total of 12 weeks even if symptoms resolve earlier. If the flare-up symptoms are persistent, your doctor may extend your Flare-up Treatment in 4-week intervals with 10 mg once daily, which must be continued until the flare-up resolves. Once the Flare-up has finished you will restart the 5 mg daily Chronic dose. For children under 14 years of age your doctor will adjust the dose based on the weight of the child.

- Flare-up treatment must be started at the first symptom indicative of a FOP flare-up. **Contact your doctor immediately to start treatment if you notice any one symptom of a flare-up.** Typically symptoms

are, for example, localised pain, soft tissue swelling/ inflammation, redness, warmth, decreased joint range of motion (movement), and stiffness. Your doctor will explain to you the signs and symptoms that you must look for.

- Flare-ups can occur in the absence of any apparent cause, but there is a high risk that major physical traumatic events can induce flare-ups and inappropriate bone formation. Examples of a traumatic event include surgery, vaccinations, injections for dental work, muscle tiredness, blunt muscle trauma from bumps, bruises, falls or influenza-like viral illnesses.
- **Contact your doctor if you experience any major physical traumatic events.** Your doctor may start you on treatment to prevent a flare-up in these cases.
- **Contact your doctor if you experience another flare-up** (new flare-up location or worsening of the original flare-up) at any time during treatment, your doctor may consider restarting the 12-week Flare-up Treatment.
- Once the flare-up has resolved, you should return to once daily Chronic Treatment. **You should not take both Chronic Treatment and Flare-up Treatment at the same time.**

Children aged from 8 years (girls) and 10 years (boys) to less than 14 years

The dose of this medicine is adjusted based on the weight of children under 14 years of age. Your doctor will prescribe the most appropriate dose based on your

child’s weight. (the dose will be increased as your child’s weight increases).

Recommended dose reduction if you experience side effects (Chronic and Flare-up treatment)

If you experience side effects during treatment, inform your doctor, who may decide to reduce your dose. The daily dose can be reduced to the next lower dose. If you are already receiving the lowest possible dose, then your doctor may stop your treatment with SOHONOS. Subsequent Flare-up Treatments must be started at the same reduced dose that was tolerated previously.

Flare-up only Treatment

If you experience side effects whilst taking Chronic daily treatment your doctor may reduce your daily dose as shown above. If after this reduction in dose you still experience side effects, then your doctor may change your treatment, so you only receive Flare-up Treatment and stop receiving Chronic Treatment completely.
The dose at Flare-up should follow the same normal recommended dose.

Children under 8 years of age (girls) and under 10 years of age (boys)

This medicine **must not** be given to girls under 8 years of age and boys under 10 years of age due to the risk of reduced bone growth.

Elderly

If you are over 65 years old your doctor may prescribe a lower dose of SOHONOS.

Precautions to be taken before handling or administering the medicine

To avoid unintended contact when handling this medicine, you must wear disposable gloves when emptying the capsule contents onto soft food. Use disposable paper towels and a container to collect waste (e.g. a resealable bag). Caregivers who are pregnant or who intend to become pregnant must avoid contact with this medicine.

When to take SOHONOS

- SOHONOS capsules should be swallowed whole and taken with food preferably at the same time each day.
- If you are unable to swallow capsules, you may open the capsules and sprinkle the content onto a teaspoon of soft food and take it immediately. If you cannot take it immediately, it can be taken after a maximum of 1 hour after the sprinkling, provided it was maintained at room temperature and not exposed to direct sunlight.

If you forget to take SOHONOS

SOHONOS should be taken regularly at the same time each day. If you miss your dose at the usual time, take the dose as soon as you remember.

If the dose has been missed by more than 6 hours, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much SOHONOS

If you think that you have taken too much SOHONOS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital, taking this leaflet with you.

You should do this even if there are no signs of discomfort or poisoning.

You may experience some of the following symptoms: severe headache, feeling sick or vomiting, feeling drowsy, irritability, and itchy skin.

5. What should I know while taking SOHONOS?

Things you should do

- Use effective contraception before, during and after taking SOHONOS (for women, unless your doctor decides this is not necessary).
- Ensure women who are pregnant or who intend to become pregnant avoid contact with SOHONOS.
- Ensure caregivers administering SOHONOS by emptying the capsule contents onto soft food avoid unintended exposure by wearing disposable gloves

when handling and use disposable paper towels and a container to collect waste (e.g. a resealable bag).

- Pregnancy, breast-feeding and fertility.
- Avoid consuming grapefruit juice or grapefruit-containing products for as long as you are taking this medicine, as they may affect the levels of SOHONOS in your blood.

This medicine should not be used if you are pregnant or trying to get pregnant as it may harm your baby. You should not breastfeed if you are taking SOHONOS, as the medicine may be passed on to your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Before starting treatment with SOHONOS your doctor will discuss contraceptive measures with you.

For more information on pregnancy and contraception, see section 2 Pregnancy Prevention.

No studies have been conducted to evaluate the effects of palovarotene on fertility in females or males.

Call your doctor straight away if you:

- think you may be pregnant.
- experience another flare-up (new flare-up location or worsening of the original flare-up) at any time during treatment. Your doctor may consider restarting the 12-week treatment.
- have concerns about your child's growth.

Remind any doctor, dentist or pharmacist you visit that you are taking SOHONOS.

Things you should not do

- Do not drink grapefruit juice or consume grapefruit-containing products while you are taking this medicine as they may affect the levels of SOHONOS in your blood.
- Do not stop taking this medicine without first speaking to your doctor.
- You should never give this medicine to another person. Please take any unused capsules to your pharmacist at the end of treatment.
- You should not donate blood during treatment with this medicine and for 1 month after stopping SOHONOS because an unborn baby could be harmed if a pregnant patient receives your blood.

Lactose intolerance

SOHONOS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SOHONOS affects you.

SOHONOS may have a minor influence on the ability to drive and use machines. SOHONOS may affect your ability to see in the dark. This condition usually clears

up after you stop taking SOHONOS, but it may persist. Therefore, SOHONOS should be used with caution.

Looking after your medicine

- Keep blister strips in the outer carton in order to protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • Nausea (feeling sick), diarrhoea, vomiting • Abdominal or stomach pain or discomfort • Heart burn • Dry mouth • Decrease in appetite **Skin related:** • Dry, scaly, or red and swollen, lips • Small raised red bumps on the skin that may easily bleed • Dry skin, skin shedding • Hair loss • Dry thickened skin that becomes cracked • Skin irritation or abrasions • Itching, itchy rash (urticaria) • Rash, burning rash, rash that appears red, purple	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
or brown which may blister • Dry, itchy, cracked and sore skin (eczema) • Skin reactions (openings or blisters), swelling with rash (dermatitis) • Fragility of the skin (may crack or break easily) • Face swelling • Bed sores(warm tender skin, swelling, pus leaking) **Eye related:** • Dry eye, red eye • Eye infection which may be red, itchy, watery or feel gritty and you may have pus (conjunctivitis) • Loss of eyelashes or eyebrows **Mental health related:** • Irritability **Other**: • Infection of the nail, or around the nail, breaking	

Less serious side effects	What to do
of the nail, ingrowing nails • Nose bleeds • Headache • Tiredness • Hot flushes • Joint pain, joint swelling • Back pain • Tiredness, shortness of breath, pale skin or noticeable heartbeats (palpitations) as this may mean you have low red blood cells (anaemia) • Excess of protein in the urine, which can be seen if you have your urine tested • Ankle fracture • High level of lipase enzyme in the blood (which can be seen in blood tests • Sunburn	

Serious side effects

Serious side effects	What to do
Infections: • Skin infection (cellulitis) may be hot, painful and swollen sometimes with fever (high temperature) and chills **Mental health related:** • Feeling depressed and having suicidal thoughts **Early closure of growth plates:** • Concern about your child's growth such as their height or limb growth (arm or leg length) **Other:** • Seizures (fits) • Fracture within the spine (vertebral fracture)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SOHONOS contains

Active ingredient **(main ingredient)**	Each capsule contains 1 mg, 1.5 mg, 2.5 mg, 5 mg or 10 mg of palovarotene
Other ingredients **(inactive ingredients)**	Capsule contents: lactose monohydrate, povidone, croscarmellose sodium, sodium lauryl sulfate, microcrystalline cellulose, magnesium stearate

	Capsule shell: gelatin, titanium dioxide Printing ink: shellac, propylene glycol, potassium hydroxide, iron oxide black

Do not take this medicine if you are allergic to any of these ingredients.

What SOHONOS looks like

SOHONOS are white, opaque, elongated, hard-gelatin capsules filled with white to off-white powder.

SOHONOS 1 mg capsules have "PVO 1" printed with black ink on the body (AUST R 394003).

SOHONOS 1.5 mg capsules have "PVO 1.5" printed with black ink on the body (AUST R 394001).

SOHONOS 2.5 mg capsules have "PVO 2.5" printed with black ink on the body (AUST R 394002).

SOHONOS 5 mg capsules have "PVO 5" printed with black ink on the body (AUST R 394000).

SOHONOS 10 mg capsules have "PVO 10" printed with black ink on the body (AUST R 393999).

SOHONOS capsules are packaged in a blister strip inside a carton.

Each pack contains 28 capsules (2 x 14 blister strips).

Australian sponsor of SOHONOS

Ipsen Pty Ltd
Level 5, 627 Chapel Street
South Yarra, VIC 3141

This leaflet was prepared in September 2025.