

WINREVAIR®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about getting this medicine, speak to your healthcare professional (doctor, nurse or pharmacist).

- ▼ This medicine is new. Please report side effects that you may experience with this medicine. See the [full CMI](#) for further details.

1. Why am I using WINREVAIR?

WINREVAIR contains the active ingredient sotatercept. WINREVAIR is used to treat adults with pulmonary arterial hypertension (PAH). PAH is a type of high blood pressure in the arteries of your lungs. For more information, see Section [1. Why am I using WINREVAIR?](#) in the full CMI.

2. What should I know before I use WINREVAIR?

Do not use if you have had an allergic reaction to WINREVAIR or any of the ingredients listed at the end of the CMI.

If your healthcare professional decides that you or a caregiver can give the injections of WINREVAIR at home, you or your caregiver should receive training from your healthcare professional on the right way to prepare and inject WINREVAIR.

Talk to your healthcare professional 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 use WINREVAIR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with WINREVAIR and affect how it works. For more information see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use WINREVAIR?

- You will use WINREVAIR every 3 weeks as an injection just under your skin (subcutaneous).
- Your dose of WINREVAIR depends on your body weight and blood tests.
- Before your first dose and regularly while using WINREVAIR, your healthcare professional will do blood tests. These are done so that your healthcare professional can monitor you and find the best dose for you.

- Your healthcare professional may adjust your dose, delay treatment, or stop treatment depending on how you respond to WINREVAIR.

More instructions can be found in Section [4. How do I use WINREVAIR?](#) in the full CMI.

5. What should I know while using WINREVAIR?

| | |
|--|---|
| <p>Things you should do</p> | <ul style="list-style-type: none"> • Remind any healthcare professional you visit that you are using WINREVAIR. • Check with your healthcare professional if you are pregnant or intend to become pregnant. Pregnancy testing is recommended before starting treatment. • Talk to your healthcare professional if you are breastfeeding or intend to breastfeed. |
| <p>Things you should not do</p> | <ul style="list-style-type: none"> • Do not change your dose or stop taking WINREVAIR without talking to your healthcare professional. |

| | |
|------------------------------------|---|
| | <ul style="list-style-type: none"> • Do not use WINREVAIR more often than your healthcare professional tells you to. |
| Looking after your medicine | <ul style="list-style-type: none"> • Store WINREVAIR in the refrigerator at 2°C to 8°C. Do not freeze. • Store in the original carton to help protect from light. |

For more information, see Section [5. What should I know while using WINREVAIR?](#) in the full CMI.

6. Are there any side effects?

Common side effects: headache, nose bleeds (epistaxis), telangiectasia (also called spider veins or tiny blood vessels that look like pink or red lines on the skin), diarrhea, dizziness, rash, increased blood pressure, redness, bleeding gums.

Serious side effects: high level of haemoglobin, low number of platelets, serious bleeding, decreased fertility. 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 healthcare professional (doctor, nurse or pharmacist) or directly at www.tga.gov.au/reporting-problems.

WINREVAIR

Sotatercept

Consumer Medicine Information (CMI)

This leaflet provides important information about WINREVAIR. You should also speak to your healthcare professional if you would like further information or if you have any concerns or questions about using WINREVAIR.

Where to find information in this leaflet:

- [1. Why am I using WINREVAIR?](#)
- [2. What should I know before I use WINREVAIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use WINREVAIR](#)
- [5. What should I know while using WINREVAIR?](#)
6. Are there any side effects?
- [7. Product details](#)

1. Why am I using WINREVAIR?

WINREVAIR contains the active ingredient sotatercept.

WINREVAIR is a prescription medicine used to treat adults with pulmonary arterial hypertension (PAH).

PAH is a type of high blood pressure in the arteries of your lungs. WINREVAIR can improve your ability to be physically active by lowering the blood pressure in your lungs.

It can also help you live longer, lower your need for a lung transplant or hospitalisation for PAH, relieve symptoms of PAH and slow down the progression of your disease. WINREVAIR is an activin receptor type IIA-Fc (ActRIIA-Fc) fusion protein which works to lower the blood pressure in your lungs.

2. What should I know before I use WINREVAIR?

Warnings

Please read this information carefully before you start to use your medicine, even if you

have just refilled your prescription. Some of the information may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

Do not use WINREVAIR if:

- you are allergic to sotatercept, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

If your healthcare professional decides that you or a caregiver can give the injections of WINREVAIR at home, you or your caregiver should receive training from your healthcare professional on the right way to prepare and inject WINREVAIR. Do not try to inject WINREVAIR until you have been shown the right way by your healthcare professional.

Your doctor will do a blood test before your first 5 doses of WINREVAIR, longer if needed, and then from time to time to check your levels of haemoglobin (a protein in red blood cells that carries oxygen) and platelets (blood cells that help blood clot). After each of these blood

tests, your healthcare provider may delay treatment or change your dose if needed.

Check with your healthcare professional if you:

- have any other medical conditions
- take any medicines for any other condition

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?](#)

Children

It is not known if WINREVAIR is safe and effective in children under 18 years of age.

Pregnancy and breastfeeding

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

- WINREVAIR may harm your unborn baby.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant while using WINREVAIR.
- Your healthcare professional should do a pregnancy test before you start using WINREVAIR.
- You should use effective birth control when using WINREVAIR.
- You should continue using effective birth control for at least 4 months after your last dose if you stop using

WINREVAIR. Ask your healthcare professional about birth control methods that would work well for you.

Talk to your healthcare professional if you are breastfeeding or intend to breastfeed.

- It is not known if WINREVAIR passes into breast milk.
- Do not breastfeed while using WINREVAIR.
- Do not breastfeed for at least 4 months after your last dose if you stop using WINREVAIR. Talk to your healthcare professional about the best way to feed your baby.

3. What if I am taking other medicines?

Tell your healthcare professional 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.

Know the medicines you take. Keep a list of them and show the list to your healthcare professional when you get a new medicine.

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

Check with your healthcare professional if you are not sure about what medicines, vitamins or supplements you are taking and if these affect WINREVAIR.

4. How do I use WINREVAIR?

Inject WINREVAIR only after you have been shown the right way by your healthcare professional.

Read the separate “Instructions for Use” booklet that comes with WINREVAIR.

How much to use

- Your dose of WINREVAIR depends on your body weight and blood tests.
- Your healthcare professional will tell you how much WINREVAIR to use and when to use it.
- Do not change your dose or stop using WINREVAIR without talking to your healthcare professional.
- Do not use WINREVAIR more often than your doctor tells you to. If you are not sure when to use WINREVAIR, call your healthcare professional.

When to use WINREVAIR

- You will use or be given WINREVAIR every 3 weeks as an injection just under your skin (subcutaneous) only in these injection sites:
 - stomach (abdomen) - at least 2 inches away from the belly button, or
 - upper thigh
 - upper arm (only if given by your healthcare professional)

- Use WINREVAIR exactly as your healthcare professional tells you to.
- You should inject WINREVAIR right away and after mixing the medicine powder with the sterile water, but no later than 4 hours after mixing.

Your healthcare professional will monitor your dose

- Your dose of WINREVAIR depends on your body weight and blood tests.
- Before your first dose and regularly while using WINREVAIR, your healthcare professional will do blood tests. These are done so that your healthcare professional can monitor you and find the best dose for you.
- Your healthcare professional may adjust your dose, delay treatment, or stop treatment depending on how you respond to WINREVAIR.

If you forget to use WINREVAIR

WINREVAIR should be used every 3 weeks. If you miss your dose at the usual time, use it within 3 days and follow your original schedule for your next dose. If not used within 3 days, call your healthcare professional for guidance.

If you miss your appointment to be given WINREVAIR, call your healthcare professional immediately to reschedule your appointment.

If you use too much WINREVAIR

If you think that you have used too much WINREVAIR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your healthcare professional, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while using WINREVAIR?

Driving or using machines

It is unlikely that this medicine will affect your ability to drive and use machines.

Drinking alcohol

Tell your healthcare professional if you drink alcohol.

Looking after your medicine

- Store WINREVAIR in the refrigerator at 2°C to 8°C. Do not freeze.
- Store in the original carton to help protect from light.
- Contact your healthcare professional if the unused vial has been out of the refrigerator for an extended period of time.

Follow the instructions on the carton on how to take care of your medicine properly.

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 and pets cannot reach it.

How long should I keep my medicine?

- Contact your healthcare professional, nurse or pharmacist if the unused injection pack has been out of the refrigerator for an extended period of time.
- After you mix the medicine powder with the sterile water (provided in the pack), it is recommended that you inject it right away.

Getting rid of any unwanted medicine

It is unlikely you will be asked to dispose of WINREVAIR. However, if you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not get 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 healthcare professional if you have any further questions about side effects.

Common side effects

| Common side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• headaches• nose bleeds (epistaxis)• telangiectasia (also called spider veins or tiny blood vessels that look like pink or red lines on the skin)• diarrhea• dizziness | Speak to your healthcare professional if you have any of these common side effects and they worry you |

| Common side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● rash ● increased blood pressure ● redness ● bleeding gums | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>High level of haemoglobin (a protein in red blood cells that carries oxygen)</p> <ul style="list-style-type: none"> ● This can raise the chance of a blood clot forming that can block a blood vessel. Your healthcare professional will do blood tests to check your haemoglobin levels before starting and regularly during treatment with WINREVAIR. <p>Low number of platelets (blood cells that help blood clot)</p> | <p>Call your healthcare professional straight away if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> • This can cause symptoms such as easy bruising, continued bleeding from cuts, and nosebleeds. Your healthcare professional will do blood tests to check your platelet level before starting and regularly during treatment with WINREVAIR. <p>Serious bleeding - Signs and symptoms:</p> <ul style="list-style-type: none"> • Persistent headache, nausea, weakness, black or tarry stool, blood in your stool, bright red blood from vomiting or coughing, persistent abdominal cramps, severe back pain, or abnormally heavy menstrual bleeding. <p>These are signs and symptoms of serious bleeding that can happen if you use WINREVAIR and are</p> | |

| Serious side effects | What to do |
|---|-------------------|
| <p>more likely to happen if you use WINREVAIR with certain medicines. Your doctor will inform you on how to recognise them. Talk to your doctor if you notice any of these signs or symptoms.</p> <p>Decreased Fertility</p> <ul style="list-style-type: none"> • WINREVAIR may decrease female and male fertility. | |

The following additional side effect has been reported in general use with WINREVAIR:

- Build-up of fluid around the heart (pericardial effusion)

Tell your healthcare professional 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 healthcare professional or pharmacist before you decide to stop using any of your medicines.

7. Product details

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

What WINREVAIR contains

| | |
|---|--|
| Active ingredient (main ingredient) | sotatercept |
| Other ingredients (inactive ingredients) | citric acid monohydrate polysorbate 80 sucrose sodium citrate dihydrate |

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

What WINREVAIR looks like

WINREVAIR medicine powder is a white to off-white lyophilized powder and may be supplied in the following single-use packaging configurations:

Vial only

- Carton containing 1 or 2 vials of WINREVAIR 45 mg powder for injection (AUST R 433670)
- Carton containing 1 or 2 vials of WINREVAIR 60 mg powder for injection (AUST R 433671)

Administration Pack

WINREVAIR 45 mg pack contains:

- 1 or 2 vials of medicine powder, 1 or 2 prefilled syringes with sterile water, 1 or 2 vial adaptors, 1 empty dosing syringe, 1 needle, 4 or 8 alcohol wipes

WINREVAIR 60 mg pack contains:

- 1 or 2 vials of medicine powder, 1 or 2 prefilled syringes with sterile water, 1 or 2 vial adaptors, 1 empty dosing syringe, 1 needle, 4 or 8 alcohol wipes

Not all presentations may be supplied.

None of the components contain natural rubber latex.

Who distributes WINREVAIR

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road

Macquarie Park NSW 2113

<http://www.msd-australia.com.au>

Tel: 1800 818 553

This leaflet was prepared in April 2026.

S-CCPPI-MK7962-I-042025

RCN: 000027947-AU

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