WINREVAIR®
Powder and Solvent for Solution for Injection

Sotatercept (45mg, 60mg)

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What Winrevair is used for

Winrevair contains the active substance sotatercept.

It is used with other therapies to treat pulmonary arterial hypertension (PAH) in **adults**. PAH is a type of high blood pressure in the arteries of your lungs. In PAH, these arteries get narrower, which makes it harder for the heart to pump blood through these vessels, and leads to symptoms like fatigue, dizziness, and difficulty breathing.

How Winrevair works

Winrevair acts on the causes of PAH responsible for the narrowing of the arteries of your lungs, which makes it easier for the heart to pump blood to your lungs and slows down the progression of your disease. It can relieve your symptoms of PAH, help you live longer and lower your need for a lung transplant or hospitalisation for PAH.

Before you use Winrevair

- *When you must not use it*

Do not use Winrevair:

- if you are allergic to sotatercept or any of the other ingredients of this medicine (listed in Product Description section).
- If the number of platelets in your blood is repeatedly very low.

- *Before you start to use it*

Warnings and precautions

Winrevair can increase the levels of haemoglobin in your blood, decrease the number of platelets in your blood, or increase the risk of serious bleeding.

Talk to your doctor or pharmacist before and while using Winrevair if you have:

- **high levels of haemoglobin in your blood** (a protein in red blood cells that carries oxygen). This can increase the chance of a blood clot forming that can block a blood vessel. Your doctor will check haemoglobin levels with regular blood tests before each of your first 5 doses of Winrevair, or longer before each dose if needed, and regularly while you are using this medicine.
- **low number of platelets in your blood** (blood cells that help blood to clot).
  This can cause easy bruising, continued bleeding from cuts and nosebleeds. Your doctor will check your number of platelets with regular blood tests before each of your first 5 doses of Winrevair, or longer before each dose if needed, and regularly while you are using this medicine. In case the number of platelets in your blood is repeatedly very low, your doctor will not start your treatment.
- **signs and symptoms of serious bleeding:**
  - 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
  - abnormally heavy menstrual bleeding

  These are signs and symptoms of serious bleeding that can happen if you take Winrevair and are more likely to happen if you take Winrevair with certain medicines. Your doctor will inform you on how to recognize them. Talk to your doctor if you notice any of these signs or symptoms. Serious bleeding could lead to hospitalisation, need for blood transfusion or other treatments, and could be life-threatening.

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years. It is not known if this medicine is safe and works in people under 18 years of age.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy:

Winrevair may harm your unborn baby.

This medicine is not recommended during pregnancy. Your doctor should do a pregnancy test before you start your treatment and you should use effective birth control

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(contraception) during your treatment and for at least 4 months after the last dose of Winrevair. Ask your doctor or pharmacist about birth control methods that would work well for you.

Tell your doctor immediately if you become pregnant or think you may be pregnant while using this medicine.

Breast-feeding:
It is not known whether Winrevair passes into breast milk. Do not breastfeed during your treatment and for at least 4 months after the last dose of Winrevair. Talk to your doctor or pharmacist about the best way to feed your baby.

Fertility:
Winrevair may decrease female and male fertility.

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

Winrevair contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

Winrevair contains polysorbate 80
This medicine contains 0.20 mg of polysorbate 80 in each mL of reconstituted solution. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

How to use Winrevair
Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- *How much to use*
Your dose
- Your dose of Winrevair depends on your body weight and blood tests. You will begin your treatment with a dose of 0.3 mg/kg, which will be increased to 0.7 mg/kg.
- Your doctor will tell you how much Winrevair to take and when to take it. It is very important that you follow the instructions from your doctor.
- Do not take Winrevair more often than your doctor tells you to. If you are not sure when to take Winrevair, talk to your doctor or pharmacist.

Your doctor will monitor your dose
- Before each of your first 5 doses, or longer before each dose if needed, and regularly while taking Winrevair, your doctor will do blood tests. This is so your doctor can monitor you and find the best dose for you.
- Your doctor may change your dose, delay treatment, or stop treatment depending on how you respond to Winrevair.

- *When to use it*
The recommended dosing schedule is one injection every 3 weeks.

- *How long to use*
Use this medicine for the duration that your doctor recommends.

- *How you will use it*
You will take Winrevair, as an injection just under your skin (subcutaneous (SC)) only in these injection sites:

- **stomach** (abdomen), at least 5 cm away from the belly button, **or**
- **upper thigh**

Note: In case your doctor or nurse is giving you the injection, they may also use your upper arm as injection site as they have received training in how to do it properly.

Before you use Winrevair
- If your doctor decides that you or your caregiver can give the injections of Winrevair at home, you or your caregiver should receive training. This training will teach you the right way to prepare and inject Winrevair. Do not try to inject Winrevair until your doctor has shown you how to do it the right way.
- Your doctor will tell you how much Winrevair to take and when to take it.
- **Read the separate "Instructions for Use"** booklet that comes with Winrevair.

- *If you use less or too much*
If you use less or more Winrevair than you should, talk to your doctor or pharmacist.

- *If you forget to use it*
If you miss your prescribed dose of Winrevair and it is within 3 days of when you should have taken it, take it immediately and follow your original schedule for your next dose. If you miss your prescribed dose of Winrevair and it is more than 3 days of when you should have taken it, your injection schedule has to be changed, talk to your doctor or pharmacist for guidance.

- *If you stop using it*

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Do not change your dose or stop taking Winrevair without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

While you are using it
- *Things you must do*
Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Winrevair.

Tell your doctor immediately if you become pregnant while using this medication.

Take Winrevair only with a doctor's prescription.

- *Things you must not do*
Do not stop using the medicine unless advised by your doctor

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Winrevair to anyone else, even if they have the same symptoms or conditions as you.

- *Things to be careful of*
Driving and using machines
It is unlikely that this medicine will affect your ability to drive and use machines.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:
Talk to your doctor or pharmacist **immediately** if you notice:

- Easy bruising, prolonged bleeding from cuts and nosebleeds. These could be signs of a low number of platelets (thrombocytopenia). This will be shown in your blood tests.

In addition, your doctor will do regular blood tests to notice whether you have:
- High levels of haemoglobin.

The serious side effects above may affect more than 1 in 10 people.

Other possible side effects:
Talk to your doctor or pharmacist if you notice any of the following:

Very common (may affect more than 1 in 10 people):
- Headache
- Nosebleeds (epistaxis)
- Spider veins or tiny blood vessels that look like pink or red lines on the skin (telangiectasia)
- Diarrhoea
- Dizziness
- Skin rash
- Bleeding gums
- Back pain
- Bleeding in the digestive system (stomach, intestine, or rectum) that may show as blood in the vomit or in the stool

Common (may affect up to 1 in 10 people):
- High blood pressure
- Redness of the skin
- Lighter or white patches on the skin (skin hypopigmentation)
- Itching at the injection site
- An infection in the urinary tract (kidney, bladder or urethra) that may cause lower back or belly pain and burning during urination.
- Fragile or widened blood vessels in the colon (colonic angioectasia)

Uncommon (may affect up to 1 in 100 people):
- Intrapulmonary shunting (a condition where blood bypasses the normal route through the lungs that can result in less oxygen delivery to the body)

Not known (frequency cannot be estimated from the available data)
- Build-up of fluid around the heart (pericardial effusion)

Reporting of side effects
Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Winrevair
- *Storage*
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original package in order to protect from light.

You should inject this medicine right away after mixing the

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medicine powder with the sterile water for injection, but no later than 4 hours after mixing.

- *Disposal*
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description
- *What it looks like*
Winrevair is a powder and solvent for solution for injection (powder for injection). The white to off-white powder comes in a 2 mL glass vial containing 45 mg or 60 mg of sotatercept. The solvent is a clear and colourless water for injections in a prefilled syringe of 1 mL or 1.3 mL.

Winrevair 45 mg is available in:
- Pack containing 1 vial 45 mg (powder), 1 prefilled syringe 1.0 mL (solvent), 1 vial adaptor, 1 dosing syringe, 1 needle and 4 alcohol wipes.
- Pack containing 2 vials 45 mg (powder), 2 prefilled syringes 1.0 mL (solvent), 2 vial adaptors, 1 dosing syringe, 1 needle and 8 alcohol wipes.

Winrevair 60 mg is available in:
- Pack containing 1 vial 60 mg (powder), 1 prefilled syringe 1.3 mL (solvent), 1 vial adaptor, 1 dosing syringe, 1 needle and 4 alcohol wipes.
- Pack containing 2 vials 60 mg (powder), 2 prefilled syringes 1.3 mL (solvent), 2 vial adaptors, 1 dosing syringe, 1 needle and 8 alcohol wipes.

- *Ingredients*
- Active ingredient
  - sotatercept. Each vial contains 45 mg or 60 mg of sotatercept. After reconstitution, each mL of solution contains 50 mg of sotatercept.
- Inactive ingredients
  - In the powder: citric acid monohydrate (E330), trisodium citrate, dihydrate (E331) (see Before you use Winrevair section "Winrevair contains sodium"), polysorbate 80 (E433) (see Before you use Winrevair section "Winrevair contains polysorbate 80") and sucrose.
  - In the solvent: water for injections.

– *MAL numbers*
WINREVAIR 45mg:
MAL26026002ACZ

WINREVAIR 60mg:
MAL26026001ACZ

Manufacturer
Patheon Italia S.p.A
Viale G.B. Stucchi, 110-20900
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Product Registration Holder
Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
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