Package leaflet: Information for the patient

Winrevair® 45 mg powder and solvent for solution for injection
Winrevair® 60 mg powder and solvent for solution for injection
sotatercept

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Winrevair is and what it is used for
2. What you need to know before you use Winrevair
3. How to use Winrevair
4. Possible side effects
5. How to store Winrevair
6. Contents of the pack and other information

1. What Winrevair is and what it 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.

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.

2. What you need to know before you use Winrevair

Do not use Winrevair
- if you are allergic to sotatercept or any of the other ingredients of this medicine (listed in section 6).
- If the number of platelets in your blood is repeatedly very low.

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.

- **build-up of fluid around the heart** (pericardial effusion).
This can cause new or worsening trouble breathing, chest discomfort, a fast or pounding heartbeat, dizziness, tiredness, or weakness. Your doctor may check for this condition if you have certain health problems or take certain medicines with Winrevair.

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.

Other medicines and Winrevair
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 (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.

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

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.

3. How to use Winrevair

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dosing schedule is one injection every 3 weeks.

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.

How you will use Winrevair
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 more Winrevair than you should
If you use less or more Winrevair than you should, talk to your doctor or pharmacist.

If you forget to use Winrevair
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 Winrevair
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.

4. Possible 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
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Winrevair

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

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.

6. Contents of the pack and other information

What Winrevair contains

- The active substance is sotatercept. Each vial contains 45 mg or 60 mg of sotatercept. After reconstitution, each mL of solution contains 50 mg of sotatercept.
- The other ingredients are
    - In the powder: citric acid monohydrate (E330), sodium citrate (E331) (see section 2 "Winrevair contains sodium"), polysorbate 80 (E433) (see section 2 "Winrevair contains polysorbate 80") and sucrose.
    - In the solvent: water for injections.

What Winrevair looks like and contents of the pack
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.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
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The following information is intended for healthcare professionals only:

Winrevair powder and solvent for solution for injection should be reconstituted before use and administered as a single injection according to patient weight (see section 4.2 of the Summary of Product Characteristics for recommended dose regimen).

See the separate Instructions for Use booklet provided together with this leaflet for detailed step by step instructions on how to prepare and administer Winrevair powder and solvent for solution for injection. An overview of the reconstitution and administration instructions is provided below.

Reconstitution instructions

- Remove the kit from the refrigerator and wait 15 minutes to allow the prefilled syringe(s) and medicinal product to come to room temperature prior to preparation.
- Check the vial to ensure the medicinal product is not expired. The powder should be white to off-white and may look like a whole or broken up cake.
- Remove the lid from the vial containing the powder and swab the rubber stopper with an alcohol wipe.
- Attach the vial adaptor to the vial.
- Visually inspect the prefilled syringe for any damage or leaks and the sterile water inside to ensure there are no visible particles.
- Break off the cap of the prefilled syringe and attach the syringe to the vial adaptor.
- Inject all of the sterile water from the attached syringe into the vial containing the powder:
  - The prefilled syringe provided with the vial 45 mg contains 1.0 mL of sterile water.
  - The prefilled syringe provided with the vial 60 mg contains 1.3 mL of sterile water.

  After reconstitution, the 45 mg vial can only provide up to a dose of 0.9 mL of medicinal product and the 60 mg vial can only provide up to a dose of 1.2 mL of medicinal product. The final concentration after reconstitution is 50 mg/mL.
- Gently swirl the vial to reconstitute the medicinal product. Do not shake or vigorously agitate.
- Allow the vial to stand for up to 3 minutes to allow bubbles to disappear.
- Visually inspect the reconstituted solution. When properly mixed, the reconstituted solution

should be clear to opalescent and colourless to slightly brownish-yellow, and should not have clumps or powder.
- Unscrew the syringe from the vial adaptor and discard the emptied syringe.
- If prescribed a 2-vial kit, repeat the steps within this section to prepare the second vial.
- Use the reconstituted solution as soon as possible, but no later than 4 hours after reconstitution.

Dosing syringe preparation

- Before preparing the dosing syringe, visually inspect the reconstituted solution. The reconstituted solution should be clear to opalescent and colourless to slightly brownish-yellow, and should not have clumps or powder.
- Swab the vial adaptor with an alcohol wipe.
- Remove the dosing syringe from its packaging and attach the syringe to the vial adaptor.
- Turn the syringe and vial upside-down and withdraw the appropriate volume for injection, based on the patient's weight.
    - If the dose amount requires the use of two vials, withdraw the entire contents of the first vial and slowly transfer the entire contents into the second vial, to ensure dose accuracy.
    - Turn the syringe and vial upside-down and withdraw the required amount of medicinal product.
- If necessary, push the plunger in to remove excess medicinal product or air from the syringe.
- Remove the syringe from the vial adaptor and attach the needle.

Administration instructions

Winrevair is to be administered as a single SC injection.
- Select the injection site on the abdomen (at least 5 cm away from navel), upper thigh, or upper arm and swab with an alcohol wipe. Select a new site for each injection that is not scarred, tender, or bruised.
    - For administration by the patient or caregiver, train them to inject only in the abdomen or upper thigh (see **"Instructions for Use"** booklet).
- Perform SC injection.
- Discard the emptied syringe. Do not reuse the syringe.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

See section 4.4 of the Summary of Product Characteristics for instructions on the traceability of biological medicinal products.

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