EMADOC-1829012207-38767
EMEA/H/C/005647

Winrevair (*sotatercept*)

An overview of Winrevair and why it is authorised in the EU

What is Winrevair and what is it used for?

Winrevair is a medicine used to improve the ability to exercise in adults with pulmonary arterial hypertension (PAH). Patients with PAH have an abnormally high blood pressure in the arteries of the lungs, causing symptoms such as breathlessness, fatigue and fainting.

Winrevair is used in combination with other PAH medicines in patients with moderate to severe limitations of physical activity (corresponding to WHO functional class II to IV).

PAH is rare, and Winrevair was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 December 2020. Further information on the orphan designation can be found on the EMA website.

Winrevair contains the active substance sotatercept.

How is Winrevair used?

Treatment with Winrevair should be started and supervised by a doctor experienced in the diagnosis and treatment of PAH. The medicine can only be obtained with a prescription.

Winrevair is available as a powder to be mixed with water to make a solution. It is given by injection under the skin of the abdomen (belly), upper arm or upper thigh, every 3 weeks. Patients or their caregiver may inject Winrevair themselves after they have been trained to do so.

Because Winrevair can increase the level of haemoglobin (the protein in red blood cells that carries oxygen around the body) and decrease the level of platelets (components that help the blood clot), the doctor will check these levels before each of the first 5 doses of Winrevair. These tests will then be repeated every 3 to 6 months. The doctor may need to adjust the dose, interrupt or stop treatment if certain side effects occur.

For more information about using Winrevair, see the package leaflet or contact your doctor or pharmacist.

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How does Winrevair work?

The active substance in Winrevair, sotatercept, attaches to and blocks a protein called activin. By doing so, it prevents the thickening and narrowing of small blood vessels in the lungs, thereby lowering blood pressure and making it easier for the heart to pump blood.

What benefits of Winrevair have been shown in studies?

A first main study showed that Winrevair was more effective than placebo (a dummy treatment) at improving the ability of adults with class II and III PAH to exercise. The main measure of effectiveness was the difference in the distance patients could walk in 6 minutes before and after treatment.

In this study, involving 323 people with class II and III PAH, after 24 weeks of treatment, Winrevair given in addition to other PAH medicines improved the distance patients could walk in 6 minutes by around 34 meters, compared with 1 meter in patients who had placebo.

A second main study in 172 people with class III and IV PAH showed that, when Winrevair was given with other PAH medicines, around 17% of people had a poor outcome, compared with around 55% of those given placebo with other PAH medicines. Poor outcomes included being admitted to hospital for more than 24 hours, lung transplantation or death.

What are the risks associated with Winrevair?

For the full list of side effects and restrictions with Winrevair, see the package leaflet.

The most common side effects with Winrevair (which may affect more than 1 in 10 people) include headache, epistaxis (nosebleed), telangiectasia (small red blood vessels in the skin), diarrhoea, increased haemoglobin levels, dizziness, back pain, rash, thrombocytopenia (low levels of blood platelets) and bleeding of the gums.

Some side effects can be serious. The most frequent serious side effects with Winrevair (which may affect up to 1 in 100 people) include thrombocytopenia, epistaxis and dizziness.

Winrevair must not be given to patients whose platelet levels are consistently low (less than 50 x 10^9/L) as it may increase the risk of bleeding. Winrevair should also not be used during pregnancy as it may harm the unborn baby.

Why is Winrevair authorised in the EU?

At the time of authorisation, existing treatments for PAH often did not control the disease well enough and people with PAH still had a shorter life expectancy, highlighting a need for additional treatments.

Winrevair was shown to improve the ability of people with PAH class II and III to exercise and to reduce the risk of poor outcomes in those with class III and IV disease.

Regarding safety, the side effects of Winrevair were considered manageable. There are limited data about the cardiovascular (affecting the heart or blood circulation) safety of Winrevair and more data are required. The company was requested to provide further results from studies with Winrevair to evaluate the cardiovascular safety of the medicine.

The European Medicines Agency therefore decided that Winrevair's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Winrevair?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Winrevair have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Winrevair are continuously monitored. Suspected side effects reported with Winrevair are carefully evaluated and any necessary action taken to protect patients.

Other information about Winrevair

Winrevair received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Winrevair can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/winrevair.

This overview was last updated in 02-2026.