swissmedic

Summary report on authorisation dated 22 June 2026

Winrevair® (active substance: sotatercept)

Indication extension in Switzerland: 5 February 2026

Powder and solvent for solution for injection for the treatment of pulmonary arterial hypertension (PAH) in adults

About the medicinal product

The medicinal product Winrevair contains the active substance sotatercept.

Winrevair was first authorised by Swissmedic on 13 September 2024 for the treatment of pulmonary arterial hypertension (PAH) in adult patients with functional class (FC) II to III according to the WHO classification.
This indication extension widens the target population to adult PAH patients in FC IV.
PAH is a rare disease with characteristic high blood pressure in the pulmonary arteries, which leads to severe limitations in physical performance and a reduced life expectancy if untreated. Winrevair inhibits the changes in the pulmonary arteries that are responsible for this, thereby slowing the progress of the disease and ultimately improving physical performance.

Winrevair has been authorised as an "orphan drug". Orphan drugs are medicinal products to treat rare diseases.

Mode of action

Winrevair selectively inhibits certain growth factors, whose hyperfunction is responsible for the disease-promoting changes to the pulmonary arteries in pulmonary arterial hypertension. This ultimately lowers blood pressure in the pulmonary arteries and reduces the load on the right side of the heart. As a result, Winrevair can improve the physical performance of patients.

Administration

Winrevair is a prescription-only medicine.

Winrevair is available as a set comprising powder and solvent (sterile water) and is reconstituted into a solution for injection before administration. The recommended starting dose is 0.3 mg per kilogram body weight and the target dose is 0.7 mg per kilogram body weight every three weeks, based on the patient's body weight. Haemoglobin levels and platelet count should be determined prior to the first dose and then at regular intervals so that the dosage can be adjusted if necessary. Winrevair should only

be used under the supervision of a doctor experienced in the diagnosis and treatment of PAH.

Efficacy

The efficacy of Winrevair was investigated in a study (ZENITH) in 172 patients with severe pulmonary arterial hypertension (PAH) with WHO function class III or IV. The participants were allocated at random to receive either Winrevair or placebo (dummy drug) every three weeks. Patients treated with Winrevair showed a significant delay to and reduction in serious events, including death, lung transplant, or hospitalisation due to worsening PAH, compared to placebo. In addition, there was an improvement in physical performance (6-Minute Walk Distance test).

Precautions, undesirable effects, & risks

Winrevair must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects (affecting more than 1 in 10 users) are nosebleeds, headache, dizziness, telangiectasia (dilation of the small blood vessels under the skin), rash, diarrhoea, elevated haemoglobin level, thrombocytopenia (decreased platelet count), and bleeding gums

Serious bleeding episodes pose an additional risk, particularly in patients who are being treated with anticoagulants at the same time, or who show a critical drop in the platelet count. Winrevair can also raise the haemoglobin level, which can increase the risk of blood clots and hyperviscosity syndrome.

Women of childbearing age should use reliable contraception during treatment and for at least 4 months after the last dose.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The study showed that the risk of serious events such as death, lung transplant, or hospitalisation was reduced significantly in patients with severe pulmonary arterial hypertension (PAH) with WHO function class III or IV who received Winrevair in combination with a standard therapy. In addition, treatment with Winrevair resulted in an improvement in physical performance and cardiac function.

Taking all the risks and precautions into account, and based on the available data, the benefits of Winrevair outweigh the risks. Swissmedic has therefore approved the indication extension for the medicinal product Winrevair, containing the active substance sotatercept, for the treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO function class (FC) IV in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Winrevair®

Information for patients (package leaflet): Information for patients Winrevair®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.