swissmedic

Summary report on authorisation dated 30 December 2024

Winrevair® (active substance: sotatercept)

Authorisation in Switzerland: 13 September 2024

Powder 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 is used in combination with a standard therapy for the treatment of pulmonary arterial hypertension (PAH) in adults. PAH is a type of high blood pressure that affects the arteries in the lungs, potentially leading to severe limitations in physical performance and a reduced life expectancy. The medicinal product aims to improve physical performance and delay the progression of the disease.

Winrevair is authorised for adult patients with PAH in WHO functional classes II to III with the following diagnoses:

- idiopathic[1] or heritable PAH or
- PAH in connection with connective tissue diseases or
- drug- or toxin-induced PAH or
- PAH after surgical correction of a congenital heart defect (shunt closure).

Since PAH is a rare and life-threatening disease, the medicinal product Winrevair has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Winrevair was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Swissmedic, and the pharmaceutical industry. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least 2 of the 5 countries.

The authorisation application for Winrevair was submitted for assessment to the regulatory authorities in Australia, Canada, Singapore, and Switzerland. Each country assessed a part of the application and then shared and

[1] Idiopathic PAH: Idiopathic means that the cause of a disease is unknown. When doctors refer to an idiopathic disease, this means that they are unable to find a specific cause or trigger for the disease despite extensive investigations. In relation to idiopathic pulmonary arterial hypertension (PAH), this means that the high blood pressure in the patients' pulmonary arteries occurs without any identifiable cause.

discussed the results. At the end of the process, each authority decided on the application independently.

Swissmedic considered the assessments by the foreign reference authorities in its decision on the authorisation.

Further details of the Access joint initiative are published on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

Winrevair contains the active substance sotatercept, which selectively blocks growth factors whose hyperfunction causes harmful changes in the pulmonary arteries. By inhibiting these growth factors, one effect of sotatercept is to prevent the progressive narrowing of the pulmonary vessels, ultimately lowering blood pressure and reducing the load on the right side of the heart. As a result, Winrevair can improve the physical performance of patients and delay disease progression.

Use

Winrevair is a prescription-only medicine.

It is available in the form of a powder that is dissolved in sterile water before use to produce a solution for injection. It is administered once every 3 weeks as a subcutaneous injection (under the skin), and the dosage is based on the patient's weight. The recommended starting dose is 0.3 mg per kg body weight, and the target dose is 0.7 mg per kg body weight. The haemoglobin level and platelet count should be determined prior to the first dose, and these parameters should be monitored regularly 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 pulmonary arterial hypertension.

Efficacy

The efficacy of Winrevair was investigated in the STELLAR study of adults with pulmonary arterial hypertension (PAH).

The 323 patients received either Winrevair or placebo (dummy drug), in addition to their existing PAH treatment.

The main aims of the study were to measure the change in the walking distance of the study participants, in the 6-Minute Walk Distance (6MWD) test, from the start of the study to Week 24, and to delay progression of the disease.

Patients who were treated with Winrevair showed a significant improvement of 40.8 metres in the 6MWD compared to the placebo group. A significant reduction in the risk of death and clinical deterioration was also observed in the Winrevair group compared to the placebo group. At Week 24, 29 % of those treated with Winrevair showed an improvement in the WHO functional class, compared to 13.8 % in the placebo group.

Precautions, undesirable effects, & risks

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

Very common undesirable effects (affecting more than 10 % of treated patients) are headache (24.5 %), nosebleeds (epistaxis) (22.1 %), dilation of small blood vessels under the skin (telangiectasia) (16.6 %), diarrhoea (15.3 %), dizziness (14.7 %), rash (12.3 %), and a decreased platelet count (thrombocytopenia) (10.4 %).

Common side effects (affecting more than 1 % but less than 10 % of treated patients) are redness of the skin, raised blood pressure, and an elevated haemoglobin level in the blood as a manifestation of increased erythrocytosis. Erythrocytosis is a condition in which too many red blood cells are produced, increasing the risk of blood clots.

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.

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

Why the medicinal product has been authorised

The aforementioned study showed that Winrevair, in combination with a standard treatment, significantly improves the physical performance of PAH patients and slows the progression of the disease. The most common side effects, such as headache, nosebleeds, and raised blood pressure, were manageable. In summary, the therapeutic benefit for the patients outweighs the risks associated with the treatment.

Based on these findings, Swissmedic has authorised the medicinal product Winrevair, containing the active substance sotatercept, in Switzerland for the treatment of PAH.

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.