swissmedic

Summary report on authorisation dated 12 November 2024

Givlaari® (active substance: givosiran)

Authorisation in Switzerland: 29 March 2021

Solution for injection for the treatment of acute hepatic porphyria (AHP) in adults and adolescents aged 12 years and older

About the medicinal product

Givlaari contains the active substance givosiran and is used for the treatment of acute hepatic porphyria in adults and adolescents aged 12 years and older.

Acute hepatic porphyria is a rare hereditary disease. It is caused by a defect in one of the proteins responsible for making a molecule called "heme" in the liver. This leads to the accumulation of some substances used in heme production, namely aminolevulinic acid (ALA) and porphobilinogen (PBG). Too much ALA and PBG can damage the nerves and cause severe attacks involving pain, nausea, muscle weakness, and changes in cognitive function. Some patients with acute hepatic porphyria also have symptoms such as pain and nausea between attacks. Long-term complications that may be observed in patients with acute hepatic porphyria include high blood pressure and chronic kidney and liver disease.

Givlaari reduces the amount of an enzyme called ALAS1, which is responsible for the production of ALA and PBG in the liver. The less ALAS1 is present in the body, the less ALA and PBG is produced by the liver. The effects of the disease can therefore be reduced.

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

Givlaari has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Givlaari in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA; reference number

EMA/62114/2020; EMEA/H/C/004775) and has only conducted a limited scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: www.ema.europa.eu.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Givlaari®

Information for patients (package leaflet): Information for patients Givlaari®

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.