swissmedic

Summary report on authorisation dated 16 December 2024

Skyclarys® (active substance: omaveloxolone)

Authorisation in Switzerland: 24 September 2024

Hard capsules for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older

About the medicinal product

The medicinal product Skyclarys contains the active substance omaveloxolone and is used for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

Friedreich's ataxia is a rare disease of the central nervous system that affects numerous organs and body functions. It is the most frequent form of genetic disorders that affect movement coordination. The first signs of the disease are coordination difficulties when walking, muscle weakness, and rapid fatigue. Friedreich's ataxia is a progressive disease. Many affected patients require a wheelchair as the disease progresses.

Since Friedreich's ataxia is a rare and life-threatening disease, Skyclarys has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Skyclarys 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 Skyclarys in Switzerland, Swissmedic accepted the assessment and approval decision of the US Food and Drug Administration (FDA) (authorisation number 216718).

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, the FDA: www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Skyclarys®

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

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.