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Public Summary SwissPAR dated 23 August 2022

Orladeyo® (active substance: berotralstat)

First authorisation in Switzerland: 7 June 2022

Medicinal product (hard capsule) for the prevention of angioedema attacks in adults and adolescents aged 12 years or older with hereditary angioedema.

Information on authorisation

Orladeyo, containing the active substance berotralstat, is used to prevent angioedema attacks in adults and adolescents aged 12 years or older who suffer from hereditary angioedema.

Hereditary angioedema, a disorder that is generally inherited, causes attacks involving swelling and pain in various parts of the body, e.g. in the hands and feet, but also sometimes in the face, lips and tongue. It can therefore restrict the affected persons' daily activities.

Since this is a rare, life-threatening disease, Orladeyo has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Orladeyo was authorised 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 the foreign regulatory agency, 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 Orladeyo in Switzerland, Swissmedic accepted parts of the assessment and approval decision of the European authority (EMA) and has not conducted its own scientific review.

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

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Orladeyo®

Information for patients (package leaflet): Patient information Orladeyo®
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 Public Summary SwissPAR.

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.