swissmedic

Public Summary SwissPAR dated 7 September 2022

Ontozry® (active substance: cenobamat)

First authorisation in Switzerland: 19 May 2022

Medicinal product (film-coated tablets) for the treatment of epilepsy in adults

About the medicine

The medicinal product Ontozry contains the active substance cenobamat and is used in combination with other antiepileptic medicines.

Ontozry is used for the adjunctive treatment of focal-onset seizures, with or without secondary generalisation, in adults whose epilepsy has not been adequately controlled despite a history of treatment with at least two antiepileptic medicines.

Focal-onset seizures are those caused by abnormal brain activity that starts in one side of the brain. Secondary generalisation means that the abnormal activity spreads to both sides of the brain.

Around 70 million people worldwide are affected by epilepsy, making it one of the most widespread severe neurological diseases.

In deciding whether to authorise the medicinal product Ontozry, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and in some cases the US Food and Drug Administration (FDA) regarding certain aspects such as the clinical data, as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.

www.ema.europa.eu
www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Ontozry®

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

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.