swissmedic

Public Summary SwissPAR dated 15 December 2022

Epidyolex® (active substance: cannabidiol)

Indication extension in Switzerland: 30 August 2022

Medicinal product (oral solution) for supportive treatment of seizures in connection with tuberous sclerosis in patients aged 2 years and over

Information on authorisation

The medicinal product Epidyolex contains the active substance cannabidiol and can be used for the treatment of seizures (epilepsy). Epidyolex is an oral solution.
The medicinal product Epidyolex is used in combination with other medicinal products for the treatment of patients aged 2 years and over with tuberous sclerosis (TSC).

Epidyolex was already authorised by Swissmedic on 10 February 2021 as a supportive treatment for seizures in patients aged 2 years and over with Lennox-Gastaut syndrome (LGS) or Dravet Syndrome (DS).

The present indication extension means that patients with seizures triggered by tuberous sclerosis can now also be treated.

Tuberous sclerosis is a disease that causes non-malignant tumours to form in various organs. More than 70% of patients with tuberous sclerosis suffer from seizures and spasms (epilepsy).

Swissmedic approved the indication extension for supportive treatment of seizures in patients aged 2 years and over with tuberous sclerosis (TSC) in Switzerland on 30 August 2022.

In deciding whether to authorise the medicinal product Epidyolex, containing the active substance cannabidiol, Swissmedic took into account the assessment of the European Medicines Agency (EMA) 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 report of a foreign partner authority, 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 product.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Epidyolex®

Information for patients:

Information for patients Epidyolex®

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.