

Public Summary SwissPAR dated 11 June 2021

Epidyolex[®] (active substance: cannabidiol)

First authorisation in Switzerland: 10 February 2021

Medicinal product (antiepileptic drug) for the adjunctive therapy of seizures for patients 2 years of age and older

About the medicinal product

The medicinal product Epidyolex contains the active substance cannabidiol, which can be used for the treatment of seizures (epilepsy). Epidyolex is an oral solution. It is used in combination with other medicines in patients

aged 2 and older with Lennox-Gastaut syndrome or Dravet syndrome. Both syndromes are rare diseases associated with seizures and fits (epilepsy).

Mode of action

The precise mechanism that causes the anti-convulsant effect of cannabidiol is not known.

Use

Epidyolex, with the active substance cannabidiol, is a prescription-only medicine. Epidyolex is supplied as a 100 ml bottle with two different dosing syringes (1 ml and 5 ml). 1 ml of liquid contains 100 mg of cannabidiol.

A distinction is made in dosing between the start of treatment (when the dose is gradually increased) and maintenance treatment (dose scheduled for long-term treatment). The doctor will determine the dosage based on body weight and the individual response.

Efficacy

In four studies 456 patients were treated with Epidyolex (221 patients with Dravet syndrome (DS) and 235 patients with Lennox-Gastaut syndrome (LGS)). The administration of Epidyolex in two dosages (10 mg per kg body weight and 20 mg per kg body

weight, per day in both cases) was compared to a dummy drug (placebo). Epidyolex was used with other epilepsy medicines.

In the two studies with DS patients, there was a reduction in the number of convulsive

seizures (serious seizures with loss of consciousness). In the two studies with LGS patients, Epidyolex also reduced the number of fall attacks (short-term loss of muscle tone and impaired consciousness, leading to sudden falling down), compared to placebo. In

all four studies, the reduction in the frequency of seizures was around 40-50% compared to 15-25% in the placebo groups.

In a long-term study, a further 644 patients were treated with Epidyolex (278 patients with DS and 366 patients with LGS).

Precautions, undesirable effects & risks

Epidyolex must not be used in people who are hypersensitive to the active substance or any of the excipients, for example sesame oil.

The following important undesirable effect should be noted: In patients who received Epidyolex, high levels of liver enzymes (elevated transaminase levels) were measured during blood tests, which can be a sign of liver injury.

The liver enzyme levels must be checked at regular intervals so that any hepatic disorders are detected.

The most common side effects (affecting more than one in 10 users) are somnolence,

decreased appetite, diarrhoea, pyrexia, fatigue and vomiting.

Taking Epidyolex together with food can increase the amount of the drug absorbed by the body. Therefore, Epidyolex should, if possible, always be taken either with or without food. If it is taken with food, the composition of the diet should be as consistent as possible.

The ability to drive and use machines is impaired during treatment with Epidyolex

All precautions, risks and other possible undesirable effects are listed in the prescribing information (Information for healthcare professionals) and the Information for patients.

Why the medicinal product has been authorised

The treatment with Epidyolex led to a proven reduction in the frequency of seizures in patients with Lennox-Gastaut syndrome or Dravet syndrome. Taking the envisaged precautions into account (including liver enzyme checks), the risks associated with Epidyolex can be viewed as acceptable.

Since both of these syndromes are rare diseases, the medicine has been authorised as an orphan drug.

The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Further information on the medicinal product

Information for healthcare professionals:

[Fachinformation Epidyolex®](#)

Information for patients:

[Patienteninformation Epidyolex®](#)

Healthcare professionals (doctors, pharmacists and others) can answer any further questions about this medicine.

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