Epidyolex®, 100 mg/ml, oral solution

Composition: Active substance: Cannabidiol. Each ml of oral solution contains 100 mg cannabidiol (100 mg/1 ml). Excipients: ethanol, sesame oil, sucralose (E955), strawberry flavour (contains benzyl alcohol).
Indication: For use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS) or with tuberous sclerosis complex (TSC) for patients 2 years of age and older.
Dosage/administration: *For LGS and DS*: Initiation of treatment: 2.5 mg/kg taken twice daily (5 mg/kg/day) for one week. Maintenance therapy: 5 mg/kg twice daily (10 mg/kg/day). Each dose can be further increased in weekly increments of 2.5 mg/kg administered twice daily (5 mg/kg/day) up to a maximum recommended dose of 10 mg/kg twice daily (20 mg/kg/day) and with adherence to the full monitoring schedule. Children and adolescents: There is no relevant use of Epidyolex in children aged below 6 months; the safety and efficacy in children aged 6 months to 2 years have not yet been established. *For TSC*: Initiation of treatment: 2.5 mg/kg taken twice daily (5 mg/kg/day) for one week. Maintenance therapy: 5 mg/kg twice daily (10 mg/kg/day). Each dose can be further increased in weekly increments of 2.5 mg/kg administered twice daily (5 mg/kg/day) up to a maximum recommended dose of 12.5 mg/kg twice daily (25 mg/kg/day) and with adherence to the full monitoring schedule. Children and adolescents: There is no relevant use of Epidyolex in children aged below 1 month; the safety and efficacy in children aged 1 month to 2 years have not yet been established. Discontinuation: the dose should be decreased gradually. Patients with impaired hepatic function, mild (Child-Pugh A): No dose adjustment is required; moderate (Child-Pugh B): Initial, maintenance, and maximum dose must be about halved compared to liver-healthy patients. A maximum dose of >10 mg/kg/day in patients with LGS and DS and of >12.5 mg/kg/day in patients with TSC is not recommended; severe (Child-Pugh C): The use is not recommended. Patients with impaired renal function: No dose adjustment required. Administration: consistently either with or without food. Oral administration is recommended; however, when necessary, nasogastric and gastrostomy tubes may be acceptable routes for enteral administration. Tubes made of polyvinyl chloride and polyurethane should not be used.
Contraindications: Hypersensitivity to the active substance or to any of the excipients. Patients with transaminase elevations >3 times the upper limit of normal (ULN) and bilirubin > 2 times the ULN.
Warnings and precautions: Epidyolex can cause dose-related elevations of liver transaminases (ALT, AST) particularly in patients taking concomitant valproate and clobazam. To consider dose adjustment or discontinuation of valproate or clobazam. Prior to starting treatment with Epidyolex, obtain serum transaminases (ALT and AST), alkaline phosphatase and total bilirubin levels; to be obtained at 2 weeks, 1 month, 2 months, 3 months and 6 months after initiation of treatment, and periodically thereafter or as clinically indicated. Upon changes in dose > 10 mg/kg/day or changes in medicinal products (dose change or additions) that are known to impact the liver, this monitoring schedule should be restarted. Discontinuation of treatment in any patients with transaminase levels > 3 times the ULN and bilirubin levels > 2 times the ULN. Can cause somnolence and sedation; increased risk for pneumonia, increase in seizure frequency; small increased risk of suicidal behaviour and ideation cannot be excluded. Contains low quantity of alcohol without noticeable effects. Benzyl alcohol may cause allergic reactions; large quantities should only be used with caution and if absolutely necessary (risk of accumulation and toxicity / «metabolic acidosis»). Sesame oil may rarely cause severe allergic reactions.
Interactions: The pharmacokinetics of Epidyolex are complex and may cause interactions with the patient's concomitant AED treatments. Epidyolex dose and/or concomitant AED treatment should therefore be adjusted during regular medical supervision and the patient should be closely monitored for adverse drug reactions.
Pregnancy/lactation: Only limited data available. Studies in animals have shown reproductive toxicity. Should not be used during pregnancy unless the potential benefit to the mother clearly outweighs the potential risk to the foetus. Breast-feeding should be discontinued during treatment.
Undesirable Effects: *Very common:* decreased appetite, somnolence, diarrhoea, vomiting, pyrexia, fatigue. *Common:* pneumonia, urinary tract infection, irritability, aggression, lethargy, seizures, cough, nausea, AST-, ALT- and GGT increased, rash, weight decreased.
Overdose: Experience is limited; mild to moderate diarrhoea and somnolence have been reported. The patient should be observed and appropriate symptomatic treatment given, including monitoring of vital signs.
Presentations: One 100 ml bottle; two 1 ml oral syringes and one bottle adaptor, two 5 ml oral syringes and one bottle adaptor (dispensing category: A). ***License number:*** 67590 (Swissmedic). ***License holder:*** DRAC AG, Murten. ***Manufacturer:*** GW Pharma Limited, Sittingbourne / UK.
For detailed information, please refer to the Swiss Compendium for Therapeutic Products Information on www.swissmedicinfo.ch.
▼This medicinal product is subject to additional monitoring. For further information please refer to the product information for Epidyolex® on www.swissmedicinfo.ch V.10/2022-01.