25 July 2019
EMA/CHMP/417900/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Epidyolex

cannabidiol

On 25 July 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Epidyolex[2], intended for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS). The applicant for this medicinal product is GW Pharma (International) B.V.

Epidyolex will be available as 100 mg/ml oral solution. The active substance of Epidyolex is cannabidiol, an antiepileptic (ATC code: N03AX). The exact mechanism of action is not fully known. Epidyolex reduces the hyperactivity of neurones through different actions: modulation of intracellular calcium via G protein-coupled receptor 55 (GPR55) and transient receptor potential vanilloid 1 (TRPV-1) channels, as well as modulation of adenosine-mediated signalling through inhibition of adenosine cellular uptake via the equilibrative nucleoside transporter 1 (ENT-1).

The benefits with Epidyolex are its ability to help manage seizures associated with LGS and DS. The most common side effects are somnolence, decreased appetite, diarrhoea, pyrexia, fatigue and vomiting.

The full indication is: "Epidyolex is indicated for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS), in conjunction with clobazam, for patients 2 years of age and older". It is proposed that Epidyolex should be initiated and supervised by physicians with experience in the treatment of epilepsy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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