31 January 2019

EMA/CHMP/808036/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ajovy

fremanezumab

On 31 January 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 Ajovy, intended for prophylaxis of migraine. The applicant for this medicinal product is Teva GmbH.

Ajovy will be available as a 225-mg solution for injection. The active substance of Ajovy is fremanezumab, an analgesic that works by binding to calcitonin gene-related peptide (CGRP).

The benefits with Ajovy are its ability to reduce the number of monthly migraine days. The most common side effects are pain and reactions at the injection site.

The full indication is: "Ajovy is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month". It is proposed that Ajovy be prescribed by physicians experienced in the treatment of migraine.

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

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