31 May 2018
EMA/CHMP/283640/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Aimovig

erenumab

On 31 May 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Aimovig, intended for prophylaxis of migraine. The applicant for this medicinal product is Novartis Europharm Limited.

Aimovig will be available as a 70-mg solution for injection. The active substance of Aimovig is erenumab, an analgesic that works by binding to calcitonin gene-related peptide (CGRP) receptors (ATC code: N02CX07).

The benefits with Aimovig are its ability to reduce number of monthly migraine days. The most common side effects are injection site reactions, constipation, muscle spasms and pruritus.

The full indication is: “Aimovig is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month”.

It is proposed that Aimovig be prescribed by physicians experienced in the diagnosis and 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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