11 November 2021
EMA/CHMP/592765/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vyepti

eptinezumab

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vyepti, intended for the prophylaxis of migraine.

The applicant for this medicinal product is H. Lundbeck A/S.

Vyepti will be available as a 100 mg concentrate for solution for infusion. The active substance of Vyepti is eptinezumab, an analgesic (ATC code: N02CD05) that works by preventing the activation of the CGRP receptors.

The benefit of Vyepti is a reduction in monthly migraine days. The most common side effects are nasopharyngitis and hypersensitivity.

The full indication is:

Vyepti is indicated for the prophylaxis of migraine in adults who have at least 4 migraine days per month.

Vyepti should 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union