24 July 2025
EMADOC-628903358-125643
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zurzuvae

zuranolone

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zurzuvae, intended for the treatment of adults with postpartum depression.

The applicant for this medicinal product is Biogen Netherlands B.V.

Zurzuvae will be available as 20 mg, 25 mg and 30 mg hard capsules. The active substance of Zurzuvae is zuranolone, an antidepressant (ATC code: N06AX31). Zuranolone is a neuroactive steroid which enhances the activity of the neurotransmitter gamma-aminobutyric acid (GABA) and is thought to exert antidepressant effects by enhancing GABAergic inhibition.

The benefits of Zurzuvae are its ability to reduce depressive symptoms in adults with postpartum depression following 2 weeks of treatment, as measured by the HAMD-17 (17-item Hamilton Rating Scale for Depression) score in a multicentre, randomised, double-blind, placebo-controlled study. The most common side effects with Zurzuvae include somnolence, dizziness and sedation.

The full indication is:

> Zurzuvae is indicated for the treatment of postpartum depression (PPD) in adults following childbirth (see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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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