14 September 2023
EMA/CHMP/404478/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zilbrysq

zilucoplan

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zilbrysq[2], intended for the treatment of Myasthenia Gravis. The applicant for this medicinal product is UCB Pharma S.A.

Zilbrysq will be available as 16.6 mg, 23 mg and 32.4 mg solutions for injection. The active substance of Zilbrysq is zilucoplan, a complement inhibitor (ATC code: L04AJ06) which blocks C5 complement-mediated activation and cell lysis.

The benefits of Zilbrysq are improvements in disease severity and function scores (Myasthenia Gravis Activities of Daily Living, Quantitative Myasthenia Gravis score and Myasthenia Gravis Composite score), and quality of life (as measured by the Myasthenia Gravis Quality of Life 15-item scale revised), as evaluated in a 12-week randomized placebo-controlled trial and its subsequent open label phase. The most common side effects are injection site reactions and upper respiratory tract infections.

The full indication is:

> Zilbrysq is indicated as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Zilbrysq should be prescribed by physicians experienced in the management of patients with neuromuscular disorders.

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 an 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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