17 September 2026
EMADOC-1829012207-70416
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Klygefa

gefurulimab

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Klygefa, intended for the treatment of adults with generalised myasthenia gravis who are anti-acetylcholine receptor (AChR) antibody positive.

The applicant for this medicinal product is Alexion Europe SAS.

Klygefa will be available as a 300 mg solution for injection in a pre-filled pen or a pre-filled syringe. The active substance of Klygefa is gefurulimab, an immunosuppressant (ATC code: L04AJ12). Gefurulimab binds to and blocks the C5 complement protein, preventing its cleavage into the pro-inflammatory anaphylatoxin C5a and C5b. This blocks the pathogenic activation of the terminal complement pathway. Gefurulimab also binds to serum albumin, extending its half-life and allowing weekly dosing.

The benefits of Klygefa are a reduction in disease severity and improvements in function, measured using the Myasthenia Gravis Activities of Daily Living, Quantitative Myasthenia Gravis and Myasthenia Gravis Composite scores, as well as improvements in quality of life, measured using the revised 15-item Myasthenia Gravis Quality of Life scale, These benefits were demonstrated with weight-based dosing in a 26-week randomised, placebo-controlled trial and its subsequent open-label phase. The most common side effects with Klygefa are injection site reactions, back pain, arthralgia, muscle spasms, myalgia nausea and vomiting.

The full indication is:

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

Klygefa is intended for use under the guidance of healthcare professionals 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

[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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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.