11 December 2025
EMADOC-1700519818-2662446
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Uplizna

inebilizumab

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Uplizna. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted a new indication as follows:[2]

> Neuromyelitis optica spectrum disorders (NMOSD)
>
> Uplizna is indicated as monotherapy for the treatment of adult patients with NMOSD who are anti-aquaporin 4 immunoglobulin G (AQP4 IgG) seropositive (see section 5.1).
>
> Immunoglobulin G4-related disease (IgG4 RD)
>
> Uplizna is indicated for the treatment of adult patients with active IgG4 RD (see section 5.1).
>
> **Generalized myasthenia gravis (gMG)**
>
> **Uplizna is indicated as an add-on to standard therapy for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive (see section 5.1).**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to 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] New text in bold

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