25 April 2025
EMA/CHMP/135941/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vyvgart

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On 25 April 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 Vyvgart. The marketing authorisation holder for this medicinal product is argenx BV.

The CHMP adopted a new indication for Vyvgart solution for injection to include treatment of adults with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy, who previously received treatment with corticosteroids or immunoglobulins. The full indications for Vyvgart solution for injection will therefore be as follows:[2]

> Vyvgart is indicated as:
>
> - an add-on to standard therapy for the treatment of adult patients with generalised Myasthenia Gravis (gMG) who are antiacetylcholine receptor (AChR) antibody positive.
> - **monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins.**

The indication for Vyvgart concentrate for solution for infusion remains unchanged and is provided in the summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated 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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