27 June 2024
EMA/CHMP/254404/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vabysmo

faricimab

On 27 June 2024, 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 Vabysmo. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to an existing indication as follows:

Vabysmo is indicated for the treatment of adult patients with:

- visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).

For information, the full indication for Vabysmo will be as follows:[2]

Vabysmo is indicated for the treatment of adult patients with:

- neovascular (wet) age-related macular degeneration (nAMD),
- visual impairment due to diabetic macular oedema (DME),
- **visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO).**

This medicine must be used by a doctor experienced in performing intravitreal injections and each vial must only be used for the treatment of one eye.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union