16 October 2025
EMADOC-1700519818-2492302
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Gazyvaro

obinutuzumab

On 16 October 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 Gazyvaro. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a new indication as follows:

> Lupus nephritis (LN)
>
> Gazyvaro in combination with mycophenolate mofetil (MMF), is indicated for the treatment of adult patients with active Class III or IV, with or without concomitant Class V, lupus nephritis (LN).

For information, the full indications for Gazyvaro will be as follows:[2]

> Chronic lymphocytic leukaemia (CLL)
>
> Gazyvaro in combination with chlorambucil, is indicated for the treatment of adult patients with previously untreated CLL and with comorbidities making them unsuitable for full-dose fludarabine based therapy (see section 5.1).
>
> Follicular lymphoma (FL)
>
> Gazyvaro in combination with chemotherapy, followed by Gazyvaro maintenance therapy in patients achieving a response, is indicated for the treatment of patients with previously untreated advanced FL (see section 5.1)
>
> Gazyvaro in combination with bendamustine followed by Gazyvaro maintenance, is indicated for the treatment of patients with FL who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen.

[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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Lupus nephritis (LN)

Gazyvaro in combination with mycophenolate mofetil (MMF), is indicated for the treatment of adult patients with active Class III or IV, with or without concomitant Class V, lupus nephritis (LN).

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.