EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMADOC-1700519818-3010835
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Venclyxto

venetoclax

On 23 April 2026, 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 Venclyxto. The marketing authorisation holder for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

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

> Venclyxto ~~in combination with obinutuzumab~~ is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) ~~(see section 5.1)~~:
>
> - **in combination with ibrutinib**
> - in combination with obinutuzumab (see section 5.1)
>
> Venclyxto in combination with rituximab is indicated for the treatment of adult patients with CLL who have received at least one prior therapy.
>
> Venclyxto monotherapy is indicated for the treatment of CLL:
>
> - in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor, or
> - in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.
>
> Venclyxto in combination with a hypomethylating agent is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy.

For information, the CHMP also adopted a change to an existing indication on 23 April 2026 to extend the use of Venclyxto in combination with acalabrutinib with or without obinutuzumab, in adults with previously untreated CLL. Information on this change is provided in a dedicated summary of opinion

[1] Summary 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, removed text as strikethrough

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available on the EMA website.

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.