19 June 2025
EMA/CHMP/200830/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Imbruvica

ibrutinib

On 19 June 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 Imbruvica. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a new indication for first-line treatment of adults with mantle cell lymphoma who are eligible for autologous stem cell transplantation. The full indications for Imbruvica will therefore be as follows:[2]

> **Imbruvica in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (Imbruvica + R-CHOP) alternating with R-DHAP (or R-DHAOx) without Imbruvica, followed by Imbruvica monotherapy, is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who would be eligible for autologous stem cell transplantation (ASCT).**
>
> Imbruvica as a single agent is indicated for the treatment of adult patients with relapsed or refractory MCL.
>
> Imbruvica as a single agent or in combination with rituximab or obinutuzumab or venetoclax is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL) (see section 5.1).
>
> Imbruvica as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with CLL who have received at least one prior therapy.
>
> Imbruvica as a single agent is indicated for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.

[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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Imbruvica in combination with rituximab is indicated for the treatment of adult patients with WM.

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.