



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2024
EMA/570665/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Blincyto

blinatumomab

On 12 December 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 Blincyto. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted an extension to an existing indication, as follows:²

BLINCYTO is indicated as monotherapy for the treatment of paediatric patients aged 1 ~~month~~^{year} or older with Philadelphia chromosome-negative CD19 positive B cell precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic haematopoietic stem cell transplantation.

BLINCYTO is indicated as monotherapy for the treatment of paediatric patients aged 1 ~~month~~^{year} or older with high-risk first relapsed Philadelphia chromosome-negative CD19 positive B-cell precursor ALL as part of the consolidation therapy (see section 4.2).

BLINCYTO is indicated as monotherapy as part of consolidation therapy for the treatment of adult patients with newly diagnosed Philadelphia chromosome negative CD19 positive B-cell precursor ALL.

For information, the full indications for Blincyto will be as follows:

BLINCYTO is indicated as monotherapy for the treatment of adults with CD19 positive relapsed or refractory B cell precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome-positive B-cell precursor ALL should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.

BLINCYTO is indicated as monotherapy for the treatment of adults with Philadelphia chromosome-negative CD19 positive B-cell precursor ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.

BLINCYTO is indicated as monotherapy for the treatment of paediatric patients aged 1 month or

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, removed text as strikethrough



older with Philadelphia chromosome-negative CD19 positive B cell precursor ALL which is refractory or in relapse after receiving at least two prior therapies or in relapse after receiving prior allogeneic haematopoietic stem cell transplantation.

BLINCYTO is indicated as monotherapy for the treatment of paediatric patients aged 1 month or older with high-risk first relapsed Philadelphia chromosome-negative CD19 positive B-cell precursor ALL as part of the consolidation therapy (see section 4.2).

BLINCYTO is indicated as monotherapy as part of consolidation therapy for the treatment of adult patients with newly diagnosed Philadelphia chromosome negative CD19 positive B-cell precursor ALL.

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.