26 March 2026
EMADOC-1700519818-2985043
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[11] (post authorisation)

Besponsa

inotuzumab ozogamicin

On 26 March 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 Besponsa. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

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

> BESPONSA is indicated as monotherapy for the treatment of adults with relapsed or refractory CD22 positive B cell precursor acute lymphoblastic leukaemia (ALL). Patients with Philadelphia chromosome positive (Ph+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI).
>
> **BESPONSA is indicated as monotherapy for paediatric patients 1 year and older with CD22-positive B cell precursor ALL: in first relapse after allo-haematopoietic stem cell transplant (HSCT); after any first relapse in patients with Very High Risk (VHR) disease (see section 5.1); after a second or greater relapse; and in those with refractory disease. Patients with Philadelphia chromosome positive (Ph+) disease should have exhausted relevant BCL-ABL targeting treatment options.**

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.

[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

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