10 November 2016
EMA/CHMP/693024/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Arzerra

ofatumumab

On 10 November 2016, 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 Arzerra. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted an extension to the existing indication as follows[2]:

"Previously untreated chronic lymphocytic leukaemia (CLL):

Arzerra in combination with chlorambucil or bendamustine is indicated for the treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine-based therapy.

See section 5.1 for further information.

Relapsed CLL:

Arzerra is indicated in combination with fludarabine and cyclophosphamide for the treatment of adult patients with relapsed CLL.

See section 5.1 for further information.

Refractory CLL:

Arzerra is indicated for the treatment of CLL in patients who are refractory to fludarabine and alemtuzumab.

See section 5.1 for further information."

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 will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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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