10 November 2022
EMA/CHMP/862821/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xofluza

baloxavir marboxil

On 10 November 2022, 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 Xofluza. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a change to the existing indications to include the treatment of paediatric patients from 1 year of age.

For information, the full indications for Xofluza will be as follows:[2]

> Treatment of influenza
>
> Xofluza is indicated for the treatment of uncomplicated influenza in patients aged **1** ~~12~~ year~~s~~ and above.
>
> Post-exposure prophylaxis of influenza
>
> Xofluza is indicated for post-exposure prophylaxis of influenza in individuals aged **1** ~~12~~ year~~s~~ and above.
>
> Xofluza should be used in accordance with official recommendations.

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, removed text as strikethrough

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