25 April 2025
EMA/136484/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xofluza

baloxavir marboxil

On 25 April 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 Xofluza. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to the existing indication to include the treatment of patients from 3 weeks of age. The indications for Xofluza will therefore be as follows:[2]

> Treatment of influenza
>
> Xofluza is indicated for the treatment of uncomplicated influenza in patients aged ~~1 year~~ **3 weeks** and above.
>
> Post-exposure prophylaxis of influenza
>
> Xofluza is indicated for post-exposure prophylaxis of influenza in individuals aged ~~1 year~~ **3 weeks** 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 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] 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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