EMA/CHMP/537072/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xofluza

baloxavir marboxil

On 12 November 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xofluza, intended for the treatment and post-exposure prophylaxis of uncomplicated influenza.

The applicant for this medicinal product is Roche Registration GmbH.

Xofluza will be available as 20-mg and 40-mg film-coated tablets. The active substance of Xofluza is baloxavir marboxil, an antiviral for systemic use (ATC code: J05AX), which is converted in the body into baloxavir. Baloxavir prevents influenza virus replication by inhibiting cap-dependent endonuclease (CEN), a virus-specific enzyme in the viral RNA polymerase complex.

The benefits of Xofluza are its ability to reduce the duration of influenza-related symptoms in healthy individuals and individuals at high risk of influenza-related complications. Following post-exposure prophylaxis with Xofluza, significantly fewer subjects developed symptomatic influenza. No major common side effects were detected in the clinical trials. Hypersensitivity reactions have been observed in the post-marketing setting, including reports of anaphylaxis and less severe hypersensitivity reactions such as urticaria and angioedema.

The full indication is:

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

Detailed recommendations for the use of this product will be described in the summary of product

[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

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characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.