21 May 2024
EMA/CHMP/228604/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fluenz

influenza vaccine (live attenuated, nasal)

On 21 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fluenz, intended for the prevention of influenza disease in children and adolescents.

The applicant for this medicinal product is AstraZeneca AB.

Fluenz will be available as a nasal spray (suspension). Fluenz is a live attenuated influenza vaccine (ATC code: J07BB03). It contains the live attenuated influenza virus strains A/(H1N1), A/(H3N2) and B from the Victoria lineage. The virus strains in the Fluenz vaccine replicate in the nasopharynx and induce a specific immune response.

The benefits with Fluenz are its ability to protect children and adolescents from 2 to less than 18 years of age against seasonal influenza via intranasal administration. The most common side effects with Fluenz are nasal congestion/rhinorrhoea, decreased appetite, headache and malaise.

The full indication is:

> Prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age.
>
> The use of Fluenz should be based on official recommendations.

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

[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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