



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2024
EMA/CHMP/452597/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Flucelvax

influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

On 17 October 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 Flucelvax, intended for the prevention of influenza disease in children and adults.

The applicant for this medicinal product is Seqirus Netherlands B.V.

Flucelvax will be available as a suspension for injection in pre-filled syringes. Flucelvax is an influenza vaccine (ATC code: J07BB02). It contains haemagglutinin and neuraminidase surface antigens from 3 inactivated influenza virus strains, two A subtypes (H1N1 and H3N2) and a B type (Victoria lineage). Flucelvax provides protection against the influenza viruses it targets by inducing neutralising antibodies against viral haemagglutinin.

The benefit of Flucelvax is its ability to protect adults and children from 2 years of age against seasonal influenza, similar to previously authorised trivalent and quadrivalent vaccine. The most common side effects with Flucelvax are pain at the injection site, headache, fatigue, myalgia, erythema and induration.

The full indication is:

Prophylaxis of influenza in adults and children from 2 years of age.

Flucelvax should be used in accordance with 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

