29 January 2026
EMADOC-1829012207-40387
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Supemtek

trivalent influenza vaccine (recombinant, prepared in cell culture)

On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Supemtek, intended for active immunisation against influenza disease in adults and children from 9 years of age.

The applicant for this medicinal product is Sanofi Winthrop Industrie.

Supemtek will be available as a solution for injection in pre-filled syringe. Supemtek is an influenza vaccine. (ATC code: J07BB02). It contains haemagglutinin proteins from three different influenza virus strains, two A subtypes (H1N1 and H3N2) and one B type. Supemtek provides active immunisation against influenza virus by inducing neutralising antibodies against viral haemagglutinin.

The benefit of Supemtek is its ability to induce an adequate immune response in adults and children from 9 years, and it has been shown to protect adults from 50 years of age and above against seasonal influenza. The most common side effects are injection-site reactions (tenderness and pain), headache, malaise, fatigue, muscle pain and joint pain.

The full indication is:

> Supemtek is indicated for active immunisation for the prevention of influenza disease in adults and children from 9 years of age and older.
>
> Supemtek 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 on the EMA website 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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