27 February 2025
EMA/CHMP/56849/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Supemtek Tetra

quadrivalent influenza vaccine (recombinant, prepared in cell culture)

On 27 February 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 Supemtek Tetra. The marketing authorisation holder for this medicinal product is Sanofi Winthrop Industrie.

The CHMP adopted an extension to the existing indication to extend the use of Supemtek Tetra to children from 9 years of age. For information, the full indication for Supemtek Tetra will be as follows:[2]

> Supemtek Tetra is indicated for active immunization for the prevention of influenza disease in adults **and children from 9 years of age and older**.
>
> Supemtek Tetra 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

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