EMA/82598/2025
EMEA/H/C/005159

Supemtek Tetra[1] *(quadrivalent influenza vaccine (recombinant, prepared in cell culture))*

An overview of Supemtek Tetra and why it is authorised in the EU

What is Supemtek Tetra and what is it used for?

Supemtek Tetra is a vaccine used to protect adults and children from 9 years of age against influenza (flu).

Influenza is mainly caused by two kinds of influenza virus, known as influenza A and B. Each of these circulate as different strains and subtypes, which change over time.

Supemtek Tetra contains proteins of four different influenza A and B virus strains (type A-H1N1, type A-H3N2 and two type B strains), chosen based on the official recommendation for the annual flu season.

How is Supemtek Tetra used?

Supemtek Tetra is available as a solution for injection in a pre-filled syringe. The recommended dose is a single injection into a muscle, preferably in the upper arm.

The vaccine can only be obtained with a prescription and should be used according to official recommendations.

For more information about using Supemtek Tetra, see the package leaflet or contact your doctor or pharmacist.

How does Supemtek Tetra work?

Supemtek Tetra is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease.

Supemtek Tetra contains proteins of four different strains of flu virus. When a person is given the vaccine, the immune system recognises the proteins as 'foreign' and makes defences against them. The immune system will then be able to respond more quickly when it is exposed to the virus. This will help to protect against the disease caused by the virus.

[1] Previously known as Supemtek

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Each year, the World Health Organization (WHO) makes recommendations on which flu strains should be included in vaccines for the upcoming flu season in the northern hemisphere. The composition of Supemtek Tetra will be updated annually according to WHO and EU recommendations.

What benefits of Supemtek Tetra have been shown in studies?

Supemtek Tetra was compared with another influenza vaccine that protects against the same four influenza A and B virus strains in 2 main studies involving over 10,000 adults. One study looked at the number of people who caught flu at least 14 days after receiving either vaccine; the other study assessed the ability of the vaccines to stimulate an immune response against influenza, by measuring the production of protective antibodies. Taken together, results of the two studies showed that Supemtek Tetra was at least as effective as the comparator vaccine at protecting against influenza in adults.

A third study involved around 1,300 people and compared the production of protective antibodies against the flu strains in the vaccine in children and adolescents with that in adults. Supemtek Tetra was shown to be at least as effective at stimulating an immune response against influenza in children and adolescents as in adults.

What are the risks associated with Supemtek Tetra?

For the full list of side effects and restrictions with Supemtek Tetra, see the package leaflet.

The most common side effects with Supemtek Tetra in adults (which may affect more than 1 in 10 people) include reactions at the site of injection (such as tenderness and pain), headache, tiredness, and muscle and joint pain. The most common side effects with Supemtek Tetra in children and adolescents aged 9 to 17 years of age (which may affect more than 1 in 10 people) include pain at the injection site, muscle pain, headache, and feeling generally unwell. In the studies, these side effects usually occurred within 3 days of vaccination and fully resolved.

Why is Supemtek Tetra authorised in the EU?

Supemtek Tetra was shown to be as effective as a comparator vaccine at protecting adults against the 4 strains included in the vaccine. In children and adolescents aged 9 to 17 years, Supemtek Tetra was shown to be at least as effective as in adults at producing antibodies against the 4 strains included in the vaccine. In terms of safety, side effects with Supemtek Tetra are similar to those observed with other influenza vaccines and are mostly mild to moderate in severity.

The European Medicines Agency therefore decided that Supemtek Tetra’s benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Supemtek Tetra?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Supemtek Tetra have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Supemtek Tetra are continuously monitored. Side effects reported with Supemtek Tetra are carefully evaluated and any necessary action taken to protect patients.

Other information about Supemtek Tetra

Supemtek received a marketing authorisation valid throughout the EU on 16 November 2020.

The name of the medicine was changed to Supemtek Tetra on 24 January 2025.

Further information on Supemtek Tetra can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/supemtek-tetra

This overview was last updated in 03-2025.