



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Supemtek (*quadrivalent influenza vaccine (recombinant, prepared in cell culture)*)

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

### What is Supemtek and what is it used for?

Supemtek is a vaccine used to protect adults 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 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 used?

Supemtek 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, see the package leaflet or contact your doctor or pharmacist.

### How does Supemtek work?

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

Supemtek 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.

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 will be updated annually according to WHO and EU recommendations.

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## **What benefits of Supemtek have been shown in studies?**

Supemtek 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 people 18 years or more of age.

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 was at least as effective as the comparator vaccine at protecting against influenza in adults.

## **What are the risks associated with Supemtek?**

The most common side effects with Supemtek (which may affect more than 1 in 10 people) are reactions at the site of injection such as tenderness and pain. In the studies, these side effects occurred within three days of vaccination and resolved without consequences.

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

## **Why is Supemtek authorised in the EU?**

Supemtek was shown to be as effective as a comparator vaccine at protecting against the 4 strains included in the vaccine. In terms of safety, side effects with Supemtek 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'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?**

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

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

## **Other information about Supemtek**

Supemtek received a marketing authorisation valid throughout the EU on 16.11.2020.

Further information on Supemtek can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/supemtek](https://ema.europa.eu/medicines/human/EPAR/supemtek)

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