

Public Summary SwissPAR dated 6 February 2023

Supemtek[®] (active substances: influenza virus haemagglutinin proteins from the strains: A(H1N1), A(H3N2), B(Yamagata) and B(Victoria))

First authorisation in Switzerland: 28 October 2021

Vaccine for the prevention of influenza (flu)

About the medicinal product

The vaccine Supemtek is used in adults to protect against influenza (flu). Flu can be caused primarily by two types of influenza virus: influenza type A and type B. The active substances in Supemtek are proteins from two different virus strains of influenza A and B (type A(H1N1), type A(H3N2), type B(Yamagata) and type B(Victoria)), which are se-

lected on the basis of the WHO's annual recommendation for the northern hemisphere. It is therefore a quadrivalent vaccine, i.e. it activates the defence system (immune system) against four different pathogens.

Supemtek is a recombinant flu vaccine, i.e. the active substances are manufactured using gene technology.

Mode of action

Vaccines stimulate the body's defences (immune system) to produce specific antibodies and increase the number of certain immune cells. When the body then encounters the pathogen, its defence system can respond more quickly. Supemtek therefore helps the

body to defend itself against certain strains of the flu virus and thus protects against influenza caused by one of these pathogens. For a more detailed explanation of how vaccines work, we recommend the [Swissmedic videos on vaccines](#).

Use

The Supemtek vaccine is only available with a prescription.

Adults aged 18 years and older receive a dose of 0.5 mL. A medical professional administers Supemtek as an injection into the

muscle at the top of the upper arm (deltoid muscle) using a pre-filled syringe. Supemtek should be used in accordance with the official vaccination recommendations.

Efficacy

The efficacy of Supemtek was investigated in two main studies (PSC12 and PSC16) with over 10,000 individuals aged 18 years and over. Supemtek was compared with another influenza vaccine (control group) that was effective against the same four influenza virus strains.

The PSC12 study showed that Supemtek was at least as effective at protecting against influenza as the vaccination in the control group.

The body's immune response (own production of special proteins) was measured after

vaccination with Supemtek or the control vaccine in both studies (PSC12 and PSC16). The immune response with Supemtek was comparable to that of the control group, although the strength of the response was not the same against all virus strains. Supemtek led to a weaker immune response to the type B/Brisbane virus strain but a stronger immune response to the type A/H3 virus strain. This type A/H3 virus strain leads to higher rates of illness and is therefore more clinically relevant.

Precautions, undesirable effects & risks

Supemtek must not be used in those who are hypersensitive to the active substances or any of the excipients.

The most frequent undesirable effects, occurring in more than one in ten users, are headache, fatigue, pain at the injection site and muscle and joint pain.

Like all vaccines, an anaphylactic reaction (acute allergic reaction) can occur following

the administration of Supemtek. Therefore, the doctor should monitor patients after the vaccination and, if necessary, initiate medical measures.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Flu vaccination is the cornerstone of public healthcare in reducing the annual burden associated with flu epidemics. Vaccination against the flu is recommended particularly for especially vulnerable individuals who have a higher risk of experiencing complications or a serious case of influenza. The studies showed that Supemtek provides effective protection against influenza caused by one

of the four virus strains. The side effects profile of Supemtek is comparable to the undesirable effects observed with other flu vaccines.

Taking all the risks and precautions into account, and based on the available data, the benefits of Supemtek outweigh the risks. Swissmedic has therefore authorised the medicinal product Supemtek in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Supemtek®](#)

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.