EMA/152765/2025
EMEA/H/C/006532

Flucelvax *(influenza vaccine [surface antigen inactivated prepared in cell cultures])*

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

What is Flucelvax and what is it used for?

Flucelvax is a vaccine used to protect adults and children from 6 months of age against influenza (flu).

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

Flucelvax contains proteins from three different inactivated influenza A and B virus strains (type A-H1N1, type A-H3N2 and one type B strain), chosen based on the official recommendation for the annual flu season.

How is Flucelvax used?

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

Flucelvax is available as an injection in a pre-filled syringe. The recommended dose is a single injection into a muscle, preferably in the upper arm, or the thigh in infants and young children. Children under 9 years of age who have not been previously vaccinated against flu should receive a second dose at least 4 weeks later.

For more information about using Flucelvax see the package leaflet or contact your doctor or pharmacist.

How does Flucelvax work?

Flucelvax is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Flucelvax contains proteins from the surface of three different strains of the flu virus.

When a person is given the vaccine, the immune system will treat the virus proteins as 'foreign' and make defences against them. If, later on, the person comes into contact with the flu, the immune system will recognise the virus proteins and be prepared to defend the body against the virus. This will help to protect against flu caused by the virus.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

What benefits of Flucelvax have been shown in studies?

The company provided data from studies carried out in previous flu seasons to support the marketing authorisation of equivalent or similar flu vaccines, Optaflu and Flucelvax Tetra. Optaflu included virus strains expected to cause flu during the 2007/2008 season, while Flucelvax Tetra includes the three virus strains of Flucelvax, as well as an additional type B strain.

A main study showed that Optaflu was more effective than placebo (a dummy treatment) at preventing flu. The study involved around 11,400 people aged 18 to 49 years who received either Optaflu, a similar flu vaccine that also protects against three virus strains, or placebo. Results showed that Optaflu reduced the number of flu cases, caused by the virus strains in the vaccine, by around 84% compared with placebo.

Two main studies involving around 5,000 people aged 4 years and older compared Flucelvax Tetra with two other vaccines that each protect against three virus strains. The immune response triggered by the vaccines was evaluated by measuring the average antibody levels and the percentage of people whose antibody levels increased significantly, three weeks after vaccination. Results showed that Flucelvax Tetra produced an immune response similar to that of the two other vaccines, leading to comparable levels of protective antibodies in people aged 9 and older.

In another study involving over 4,500 children aged from 2 to less than 18 years of age, Flucelvax Tetra was found to be effective in preventing flu. The study compared Flucelvax Tetra to a non-influenza vaccine. Flucelvax Tetra reduced the cases of flu: 7.8% of children vaccinated with Flucelvax Tetra got flu compared with 16.2% of those given the non-influenza vaccine.

A study involving around 5,700 children aged from 6 months to less than 4 years of age compared Flucelvax Tetra (1 or 2 doses, depending on whether they had received a past flu vaccination) with a non-influenza vaccine. Flucelvax Tetra was found to reduce the risk of getting flu: around 3.6% (104 out of 2856) of children vaccinated with Flucelvax Tetra got flu from any type of flu virus compared with 6.1% (173 out of 2835) of those given the non-influenza vaccine. Around 1.5% (44 out of 2856) of children vaccinated with Flucelvax Tetra got flu caused from virus strains specifically targeted by the vaccine, compared with around 2.9% (82 out of 2835) of children vaccinated with the non-influenza vaccine.

What are the risks associated with Flucelvax?

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

The most common side effects with Flucelvax in adults (which may affect more than 1 in 10 people) include pain, reddening and hardening at the site of injection, headache, tiredness and muscle pain.

The most common side effects in children aged 6 to less than 18 years of age with Flucelvax (which may affect more than 1 in 10 children) include pain, reddening, hardening, and bruising at the injection site, tiredness, muscle pain, headache and loss of appetite.

The most common side effects in children aged 6 months to less than 6 years of age with Flucelvax (which may affect more than 1 in 10 children) include tenderness, reddening, hardening and bruising at the injection site, sleepiness, irritability, fever, diarrhoea and change in eating habits.

Flucelvax must not be used in people who are allergic to the active substance, any of the other ingredients, or the following substances which may be present in the vaccine in trace amounts: beta-propiolactone, cetyltrimethylammonium bromide and polysorbate 80.

Why is Flucelvax authorised in the EU?

Each year in Europe, seasonal flu causes up to 50 million cases of illness, and between 15,000 and 70,000 people die from flu-related causes. The effectiveness of Flucelvax in people aged 6 months of age and older is supported by studies for similar or equivalent vaccines used during previous flu seasons that have a similar composition and are made using the same process. These studies have shown that the vaccines trigger a strong immune response to protect against flu and are effective in preventing flu. The safety profile of Flucelvax is expected to be similar to these vaccines, with side effects that are generally mild to moderate and short lived.

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

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

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

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

Other information about Flucelvax

Flucelvax received a marketing authorisation valid throughout the EU on 15 November 2024.

Further information on Flucelvax can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/flucelvax.

This overview was last updated in 04-2025.