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

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

What is Flucelvax Tetra and what is it used for?

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

Flu 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.

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

How is Flucelvax Tetra used?

Flucelvax Tetra is available as an injection in a pre-filled syringe. The recommended dose is one single injection into a muscle (0.5 ml). A second dose should be given at least 4 weeks later to children less than 9 years of age who have not been previously vaccinated against flu.

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

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

How does Flucelvax Tetra work?

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

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When a person is given the vaccine, the immune system will treat the virus proteins as 'foreign' and makes defences against them. If, later on, the vaccinated person comes into contact with the virus, the immune system will recognise the virus proteins and be prepared to attack it. 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 Flucelvax Tetra will be updated annually according to WHO and EU recommendations. Historically, seasonal flu vaccines have contained three strains of flu: one influenza A-H1N1 virus, one influenza A-H3N2 virus, and one influenza B virus. Flucelvax Tetra includes an additional B virus strain.

What benefits of Flucelvax Tetra have been shown in studies?

Flucelvax Tetra has been found to be effective in adults and children from 6 months of age.

Two main studies in over 5,000 people from 4 years of age found that Flucelvax Tetra stimulated an immune response against influenza that was similar to that of two comparator vaccines, leading to similar levels of protective antibodies in people from 9 years of age. One of the comparator vaccines was Optaflu, a previously authorised vaccine which contains three of the four strains of influenza in Flucelvax Tetra and whose effectiveness in preventing flu was well established. The other vaccine is based on Optaflu but contains the other B strain of Flucelvax Tetra. Together the comparator vaccines contain the four strains of influenza in Flucelvax Tetra.

In children aged from 2 to less than 18 years of age, Flucelvax Tetra was found to reduce the risk of getting flu. In a study in over 4,500 children, compared 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 5,691 children 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: 3.6% of children vaccinated with Flucelvax Tetra got flu compared with 6.1% of those given the non-influenza vaccine.

What are the risks associated with Flucelvax Tetra?

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

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

In adolescents and children over 6 years of age, additional side effects included bruising at the injection site and loss of appetite, which were seen in more than 1 in 10 people.

In children from 6 months up to 6 years of age, the most common side effects with Flucelvax Tetra (which occurred in more than 1 in 10 children) included tenderness, redness, hardening and bruising at the injection site, sleepiness, irritability, changes in eating habits, diarrhoea and fever.

Flucelvax Tetra must not be used in people who are hypersensitive (allergic) to any of the components of the vaccine, or to any substances found at trace (very low) levels in the vaccine.

Why is Flucelvax Tetra authorised in the EU?

Flucelvax Tetra is effective at stimulating immune responses against the strains included in the vaccine and preventing flu in adults and children from 6 months of age. The inclusion of two influenza B strains in Flucelvax Tetra can provide a broader protection against influenza B. In terms of safety, side effects with Flucelvax Tetra are similar to those observed with vaccines containing three influenza strains and are mostly mild to moderate in severity.

The European Medicines Agency therefore decided that Flucelvax 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 Flucelvax Tetra?

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

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

Other information about Flucelvax Tetra

Flucelvax Tetra received a marketing authorisation valid throughout the EU on 12 December 2018.

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

This overview was last updated in 01-2025.