



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Fluenz Tetra

influenza vaccine (live attenuated, nasal)

This is a summary of the European public assessment report (EPAR) for Fluenz Tetra. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fluenz Tetra.

For practical information about using Fluenz Tetra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fluenz Tetra and what is it used for?

Fluenz Tetra is a vaccine used to protect children from 2 to less than 18 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 circulates as different strains or subtypes, which change over time. Fluenz Tetra will contain live attenuated (weakened) influenza A and B virus strains (type A-H1N1, type A-H3N2, and two type B strains) based on the official recommendation for the annual flu season.

How is Fluenz Tetra used?

Fluenz Tetra is available as a nasal spray. The recommended dose is one nasal spray (0.1 ml) per nostril. Children who have not been previously vaccinated against seasonal influenza should receive a second dose 4 weeks after the first.

The vaccine can only be obtained with a prescription. Its use should be based on official recommendations.



How does Fluenz Tetra work?

Fluenz Tetra is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Fluenz Tetra contains strains of flu virus that have first been weakened so that they do not cause disease.

When a person is given the vaccine, the immune system recognises the virus as 'foreign' and makes defences against it. The immune system will then be able to respond more quickly when it is exposed to the virus again. 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 two A and two B strains in Fluenz Tetra will be updated with weakened virus strains for each season, according to WHO and European Union recommendations. Historically, seasonal flu vaccines have contained three strains of influenza: one influenza A-H1N1 virus, one influenza A-H3N2 virus, and one influenza B virus. The inclusion of both influenza B viruses in Fluenz Tetra can provide a broader protection against influenza B.

The viruses used in Fluenz Tetra are grown in hens' eggs.

What benefits of Fluenz Tetra have been shown in studies?

The company provided three studies that compared Fluenz Tetra with Fluenz, an authorised influenza vaccine that contains three of the four strains of influenza in Fluenz Tetra and whose effectiveness is already established.

Of these studies the main study involved over 2,000 children aged 2 to 17 years who were vaccinated with either Fluenz Tetra or one of two Fluenz vaccines containing either one of the two influenza B strains which are also contained in Fluenz Tetra. The study assessed the ability of the vaccines to stimulate an immune response against influenza, by measuring the production of protective antibodies. The study showed that patients vaccinated with Fluenz Tetra had immune responses against each of the four vaccine virus strains that were comparable to the immune responses stimulated by the Fluenz vaccines.

What are the risks associated with Fluenz Tetra?

The most common side effects with Fluenz Tetra (seen in more than 1 patient in 10) are reduced appetite, headache, blocked or runny nose and malaise (feeling unwell). For the full list of all side effects reported with Fluenz Tetra, see the package leaflet.

Fluenz Tetra must not be used in children who are hypersensitive (allergic) to the active substances or any of the other ingredients, to gentamicin (a type of antibiotic), or to eggs or egg proteins. It must also not be given to children with a weakened immune system due to conditions such as blood disorders, symptomatic HIV infection, cancer or certain medical treatments, nor to children who are receiving treatment with salicylates (painkillers such as aspirin).

Why is Fluenz Tetra approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Fluenz Tetra's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the immune response stimulated by Fluenz Tetra was similar to the immune response stimulated by Fluenz. In addition, the CHMP considered the fact that the vaccine is given by nasal

spray and not by injection and the fact that both influenza B viruses are included in the vaccine to be important advantages for children. The safety profile of Fluenz Tetra is similar to Fluenz and was considered acceptable.

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

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

Other information about Fluenz Tetra

The European Commission granted a marketing authorisation valid throughout the European Union for Fluenz Tetra on 4 December 2013.

The full EPAR for Fluenz Tetra can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports). For more information about treatment with Fluenz Tetra, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2016.