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Fluad Tetra *(influenza vaccine (surface antigen, inactivated, adjuvanted))*

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

What is Fluad Tetra and what is it used for?

Fluad Tetra is a vaccine used to protect people aged from 65 years against influenza (flu).

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

Fluad Tetra will contain proteins from four different inactivated influenza A and B virus strains (two strains of type A influenza virus of the subtypes H1N1 and H3N2 and two type B strains). They are chosen according to the official recommendation for the annual flu season.

The vaccine also contains an adjuvant, which helps to improve the vaccine's effectiveness. The viruses used for producing Fluad Tetra are grown in fertilized hens' eggs.

How is Fluad Tetra used?

Fluad Tetra is available as an injection in a pre-filled syringe. The recommended dose is a single injection (of 0.5 ml) into a muscle, preferably in the upper arm.

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

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

How does Fluad Tetra work?

Fluad Tetra is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease. Fluad Tetra contains small amounts of proteins of influenza viruses. When a person is given the vaccine, the immune system recognises the proteins in the vaccine as 'foreign' and makes antibodies against them. If the person then comes into contact with the virus, these antibodies, together with other components of the immune system, will be able to fight off the virus more effectively and so help to protect the person against the flu.

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Each year, the World Health Organization (WHO) recommends which flu strains should be included in flu vaccines for the upcoming flu season in the northern hemisphere. The composition of Fluad Tetra will be updated annually according to WHO and EU recommendations.

What benefits of Fluad Tetra have been shown in studies?

Studies in people aged 65 years or more investigated the effectiveness of Fluad Tetra at triggering the production of protective antibodies against flu.

A study, involving over 7,000 people, found that antibody levels were generally higher when an adjuvant was included in the vaccine. The study compared an influenza vaccine that did not contain an adjuvant with one that contained the same adjuvant as Fluad Tetra. Both vaccines contained three of the four virus strains covered by Fluad Tetra.

Another study, involving 1,776 people, found that after 22 days the level of antibodies resulting from Fluad Tetra vaccination were similar to those resulting from two other vaccines, each containing both influenza A virus strains and either one of the influenza B virus strains. All vaccines contained the same adjuvant.

The company also presented information on the use of Fluad Tetra in children aged between 6 months and 6 years, but it withdrew its application for this use. Results from these studies did not clearly show that Fluad Tetra was sufficiently effective for protecting children against influenza.

What are the risks associated with Fluad Tetra?

The most common side effects with Fluad Tetra (which may affect more than 1 in 10 people), which generally last up to 3 days, are pain at the injection site, tiredness and headache.

Fluad Tetra must not be used in people allergic to the active substances or any of the other ingredients or to the following substances which may be present in the vaccine in trace amounts: ovalbumin (egg protein), the antibiotics kanamycin and neomycin, formaldehyde, cetyltrimethylammonium bromide or hydrocortisone.

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

Why is Fluad Tetra authorised in the EU?

In patients aged 65 years and over, Fluad Tetra stimulates a higher level of antibody production than influenza vaccines that do not contain an adjuvant. Because Fluad Tetra includes two influenza B virus strains, it can give broader protection than previous vaccines that contained only one strain. Side effects of Fluad Tetra are mostly mild to moderate and last only a short time.

The European Medicines Agency therefore decided that Fluad 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 Fluad Tetra?

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

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

Other information about Fluad Tetra

Fluad Tetra received a marketing authorisation valid throughout the EU on 20 May 2020.

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

This overview was last updated in 05-2020.