



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 50 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 contains proteins from four different inactivated influenza A and B virus strains (type A H1N1, type A 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 in Fluad Tetra are grown in fertilised hens' eggs.

How is Fluad Tetra used?

Fluad Tetra is given as a single injection 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 issued at national level by public health bodies.

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. The immune system will then be able to respond more quickly when exposed to the virus. This will help to protect against flu.

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.

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

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What benefits of Flud Tetra have been shown in studies?

Studies in people aged 50 years or more investigated the effectiveness of Flud Tetra at triggering the production of protective antibodies against flu.

A study involving over 7,000 people aged 65 years or above 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 Flud Tetra. Both vaccines contained three of the four virus strains covered by Flud Tetra.

A second study involving 1,776 people aged 65 years or above found that after 22 days the level of antibodies resulting from Flud Tetra vaccination was similar to that resulting from two other vaccines, each containing both influenza A virus strains and either one of the influenza B virus strains contained in Flud Tetra. All vaccines contained the same adjuvant.

Another study involved 2,044 people aged 50 to 64 years who received either Flud Tetra or another influenza vaccine also containing four virus strains, but no adjuvant. Three weeks after vaccination, the level of antibodies produced against each of the four virus strains in response to Flud Tetra vaccination was similar to that seen with the comparator vaccine. Further results showed that, compared with the comparator vaccine, Flud Tetra vaccination led to higher levels of antibodies, although not against all 4 virus strains.

However, additional data showing that, in people aged 50 to 64 years, vaccination with an influenza vaccine containing three virus strains and an adjuvant produced higher antibody levels than vaccination with a comparable vaccine that did not contain an adjuvant. Further evidence from observational studies and public health monitoring also supports the effectiveness of influenza vaccines containing an adjuvant in the 50-64 years age group.

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

What are the risks associated with Flud Tetra?

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

The most common side effects with Flud Tetra (which may affect more than 1 in 10 people), which generally last up to 3 days, include pain at the injection site, tiredness and headache. In people aged 50 to less than 65 years, other common side effects include arthralgia (joint pain) and myalgia (muscle pain).

Flud 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.

The vaccine must also not be used by people who have had anaphylaxis (a sudden, severe allergic reaction) to previous influenza vaccination.

Why is Flud Tetra authorised in the EU?

In people aged 65 years and over, Flud Tetra stimulates a higher level of antibody production than influenza vaccines that do not contain an adjuvant. The vaccine is also expected to be effective in people aged 50 to less than 65 years. Because Flud Tetra includes two influenza B virus strains, it can

give broader protection than previous vaccines that contained only one strain. Side effects of Flud Tetra are mostly mild to moderate and last only a short time.

The European Medicines Agency therefore decided that Flud 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 Flud Tetra?

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

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

Other information about Flud Tetra

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

Further information on Flud Tetra can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/flud-tetra.

This overview was last updated in 07-2024.