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

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

What is Fluad and what is it used for?

Fluad is a vaccine used to protect people from 50 years of age 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 contains proteins from three different inactivated influenza A and B virus strains (type A H1N1, type A H3N2 and one type B strain). 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 are grown in fertilised hens' eggs

How is Fluad used?

Fluad can only be obtained with a prescription and should be used according to official recommendations issued at national level by public health bodies.

The vaccine is given as a single injection into a muscle, preferably in the upper arm.

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

How does Fluad work?

Fluad is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a specific disease. Fluad contains small amounts of proteins from the surface of three different strains of flu virus.

When a person is given the vaccine, the immune system recognises the proteins in the vaccine as 'foreign' and makes antibodies 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.

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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 will be updated annually according to WHO and EU recommendations.

What benefits of Fluad have been shown in studies?

A main study involving over 7,000 people aged 65 years or older, compared the immune response triggered by Fluad with that of a flu vaccine targeting the same virus strains, but without an adjuvant. 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. Those vaccinated with Fluad had on average, a stronger immune response compared with those who received the non-adjuvanted flu vaccine.

The benefits of Fluad in people aged 50 to 64 years are based on data from a main study with Fluad Tetra, a flu vaccine that protects against four flu strains expected to cause flu in previous seasons. Fluad includes one less B strain than Fluad Tetra. The study involved 2,044 people aged 50 to 64 years who received either Fluad Tetra or another flu vaccine also containing four virus strains, but no adjuvant. The immune response triggered by the vaccines was evaluated by measuring the average antibody levels against the virus strains and the percentage of people whose antibody levels increased significantly, three weeks after vaccination. Those vaccinated with Fluad Tetra had on average, a stronger immune response compared with those who received the non-adjuvanted vaccine.

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.

What are the risks associated with Fluad?

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

The most common side effects with Fluad (which may affect more than 1 in 10 people), which generally last up to three days, include pain and tenderness at the injection site, tiredness and headaches. In people aged 50 to 65 years, other common side effects include joint and muscle pain. These side effects are usually mild or moderate in intensity and resolve within 3 days after vaccination.

Fluad must not be used in people allergic to the active substances, any of its 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 vaccines.

Why is Fluad authorised in the EU?

Fluad stimulates a stronger immune response than flu vaccines that do not contain an adjuvant. The effectiveness of Fluad in people aged 50 years and older is also supported by studies for similar vaccines used during previous flu seasons, such as Fluad Tetra, which have a similar composition and are made by the same process. These studies have shown that the vaccines trigger a strong immune response, which is expected to protect against the flu. Side effects with Fluad are generally mild to moderate and last only a short time.

The European Medicines Agency therefore decided that Fluad'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 Fluad?

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

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

Other information about Fluad

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

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

This overview was last updated in 11-2024.