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Aflunov (*zoonotic influenza vaccine* [*H5N1*] [*surface antigen, inactivated, adjuvanted*])

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

What is Aflunov and what is it used for?

Aflunov is a vaccine used in adults and children above the age of 6 months to protect against flu caused by the H5N1 ('bird flu') strain of the influenza A virus. Aflunov contains parts of influenza (flu) viruses that have been inactivated (killed). Aflunov contains parts from a flu strain called A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23). (clade 2.2.1).

How is Aflunov used?

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

The vaccine is given by injection into the muscle of the thigh or shoulder in two doses, at least 3 weeks apart. In an officially declared pandemic caused by the H5N1 strain of influenza A, people who have already been vaccinated with Aflunov (with one or two doses) may be given only one more dose, instead of the two doses recommended for unvaccinated people.

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

How does Aflunov work?

Aflunov is a vaccine to be given before or during a flu pandemic to protect against a new strain of flu. A flu pandemic happens when a new strain of the flu virus can spread easily from person to person, because people do not have immunity (protection) against it. Health experts are concerned that a future flu pandemic could be caused by the H5N1 strain of the virus, an infection that can spread from birds to humans (a 'zoonotic' infection).

Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a specific disease. This vaccine contains some parts of the H5N1 virus. The virus has first been inactivated so that it does not cause any disease. When a person is given the vaccine, the immune system recognises the virus parts in the vaccine as 'foreign' and makes antibodies against them. When

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the person comes into contact with the virus, these antibodies, together with other components of the immune system, will be able to kill the virus and help protect against the disease.

The vaccine contains an 'adjuvant' (a compound containing oil) to increase the vaccine's effectiveness.

What benefits of Aflunov have been shown in studies?

Aflunov has been shown to produce sufficient antibodies to stimulate an immune response and protect against H5N1.

At the time of the initial marketing authorisation, two main studies using a strain called A/Vietnam/1194/2004 (H5N1)-like strain (NIBRG-14) provided data on vaccination with Aflunov in healthy adults aged below and above 60 years. In one study involving 3,372 people, subjects were given either a seasonal flu vaccine followed by two doses of Aflunov 3 weeks apart, or placebo (a dummy vaccine) followed by two doses of a seasonal flu vaccine 3 weeks apart. In this study, 21 days after the second injection, around 90% of people aged below 60 years and around 80% of those aged above 60 years had levels of antibodies that would protect them against H5N1.

In the second study 240 adults were given Aflunov using different vaccination schedules. The studies looked at the ability of the vaccine to trigger the production of antibodies ('immunogenicity') against the flu virus. This study established that Aflunov should be given as two doses at least 3 weeks apart.

A third study, using a vaccine with strain A/turkey/Turkey/1/2005 (H5N1)-like strain (NIBRG-23), was carried out in 343 adults aged below and above 60 years. The study showed that 21 days after the second injection, around 70% of adults below 60 years and around 64% of adults above 60 years produced an acceptable antibody response.

A study carried out in 420 children aged between 6 months and 8 years of age received two doses of Aflunov given 3 weeks apart. The vaccine was shown to bring about protective levels of antibodies to a satisfactory level. In an additional study Aflunov was also found to produce protective levels of antibodies in children aged 6 months to 17 years.

What are the risks associated with Aflunov?

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

The most common side effects with Aflunov in adults (which may affect more than 1 person in 10) are headache, myalgia (muscle pain), reactions at the site of injection (swelling, pain, hardening and redness), tiredness, malaise (generally feeling unwell) and chills.

In addition, in children aged 3 to 17 years of age the most common side effects may also include nausea (feeling sick), diarrhoea and vomiting, sweating, injection site tenderness and bruising.

In children between the age of 6 months and 35 months of age fever, reactions at the site of injection (swelling, bruising, hardening and redness), irritability, tenderness, unusual crying, sleepiness, change in eating habits, diarrhoea, fever, vomiting and sweating are the most common side effects.

Aflunov must not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, including those found at trace (very low) levels (egg or chicken protein, ovalbumin [a protein in egg white], kanamycin or neomycin [antibiotics], formaldehyde and cetyltrimethylammonium bromide). However, it may be appropriate to give the vaccine to these people during a pandemic, as long as facilities for resuscitation are available.

Why is Aflunov authorised in the EU?

It was noted that it is likely that a H5N1 strain of influenza will cause a pandemic in the future and Aflunov was shown to produce sufficient antibodies to stimulate an immune response and protect against H5N1. The safety profile was also considered acceptable. tThe European Medicines Agency therefore decided that Aflunov'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 Aflunov?

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

As for all medicines, data on the use of Aflunov are continuously monitored. Side effects reported with Aflunov are carefully evaluated and any necessary action taken to protect people who receive Aflunov.

Other information about Aflunov

Aflunov received a marketing authorisation valid throughout the EU on 29 November 2010.

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

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