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Aujemflu (*influenza vaccine (surface antigen, inactivated, adjuvanted, prepared in cell culture)*)

A plain-language overview of Aujemflu and why it is authorised in the EU

What is Aujemflu and what is it used for?

Aujemflu is a vaccine to protect adults aged 50 years and older against flu (influenza).

Seasonal influenza epidemics are mainly caused by two types of influenza virus, known as influenza A and B. Each of these circulate as different subtypes or lineages, which change over time.

Aujemflu contains inactivated influenza virus strains: two type A viruses (subtypes A-H1N1 and A-H3N2) and one type B virus (Victoria lineage), which are selected in accordance with the official recommendation for the annual flu season.

The vaccine also contains an adjuvant, which helps to improve the vaccine's effectiveness.

How is Aujemflu used?

Aujemflu is given as an injection into the upper arm muscle (deltoid). It is suitable for adults aged 50 years and above and should be given by a healthcare professional.

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

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

How does Aujemflu work?

Aujemflu is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Aujemflu 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.

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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 virus strains in Aujemflu are updated for each season based on this official recommendation. This helps to protect against the disease caused by the virus for the upcoming flu season.

What benefits of Aujemflu have been shown in studies?

The effectiveness of Aujemflu has been studied in 7,699 adults 50 years of age and older. The main study compared Aujemflu with two other influenza vaccines already used for this age group. All three vaccines targeted influenza virus strains that included A/H1N1, A/H3N2, and B/Victoria. However, Aujemflu contained proteins from these strains at a higher concentration. Of the two comparator vaccines, one included an adjuvant and the other did not.

The benefit of Aujemflu was measured by how well it stimulated the body to produce antibodies against the strains of influenza virus contained in the vaccine.

The results showed that, four weeks after vaccination, people who received Aujemflu had high levels of antibodies against all targeted strains of the flu virus. The immune response to Aujemflu was comparable to that produced by the comparator vaccines.

Studies carried out with Aujemflu are described in more detail in the medicine's assessment reports.

What are the side effects and restrictions with Aujemflu?

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

The most common side effects with Aujemflu (which may affect more than 1 in 10 people) include injection site pain, tiredness, headache, arthralgia (joint pain) and myalgia (muscle pain).

Aujemflu must not be used in people who are 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: beta-propiolactone and cetyltrimethylammonium bromide. The vaccine must also not be used by people who have had anaphylaxis (a sudden, severe allergic reaction) to a previous influenza vaccination.

Why is Aujemflu authorised in the EU?

In adults aged 50 and above, Aujemflu provided a particularly strong response against both influenza A and B strains included in the vaccine. Although the study included a different version of Aujemflu that was active against four influenza virus strains, the data are considered fully applicable to Aujemflu.

The European Medicines Agency concluded that the vaccine produces an effective immune response against influenza and has an acceptable safety profile. It therefore decided that Aujemflu'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 Aujemflu?

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

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

Other information about Aujemflu

Aujemflu received a marketing authorisation valid throughout the EU on 20 August 2026.

Further information on Aujemflu, including the package leaflet and assessment report(s), can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/aujemflu .

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 08-2026.