

**PACKAGE LEAFLET**  
**Package leaflet: Information for the user**

**Aujemflu**  
**Suspension for injection in pre-filled syringe**  
Adjuvanted Trivalent Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Aujemflu is and what it is used for
2. What you need to know before you receive Aujemflu
3. How Aujemflu is given
4. Possible side effects
5. How to store Aujemflu
6. Contents of the pack and other information

**1. What Aujemflu is and what it is used for**

Aujemflu is a vaccine against flu (influenza) for adults 50 years of age and older.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause flu.

Aujemflu contains an adjuvant (a substance which is intended to boost your immune system's response to the vaccine). The vaccine is prepared in cell culture and, therefore, is egg-free.

The vaccine targets three strains of influenza virus following the recommendations by the World Health Organisation for the 2025/2026 Season.

**2. What you need to know before you receive Aujemflu**

**You should not receive Aujemflu:**

- if you are allergic to
  - the active ingredients or any of the other ingredients of this medicine (listed in section 6),
  - beta-propiolactone, cetyltrimethylammonium bromide (CTAB) and polysorbate 80, which are trace residues from the manufacturing process.
- if you have had a severe allergic reaction (e.g., anaphylaxis) to previous influenza vaccination.

## **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before receiving Aujemflu.

### **BEFORE receiving this vaccine**

- Your doctor or nurse will make sure that appropriate medical treatment and supervision is readily available in case of a rare anaphylactic reaction (a very severe allergic reaction with symptoms such as difficulty in breathing, dizziness, a weak and rapid pulse and skin rash) after Aujemflu is given.
- You should tell your doctor or nurse if you are feeling nervous about the vaccination process or have ever fainted following an injection.
- You should tell your doctor or nurse if you have an acute illness which includes fever as a symptom. Your doctor may decide to delay your vaccination until your fever is gone. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- You should tell your doctor or nurse if you have a bleeding problem, bruise easily or you use a medicine to prevent blood-clots.
- You should tell your doctor or nurse if your immune system is impaired, or if you are having treatment that affects the immune system, e.g., with medicine against cancer (chemotherapy) or corticosteroid medicines (see section “Other medicines and Aujemflu”).

As with all vaccines, Aujemflu may not fully protect all persons who are vaccinated.

Inflammation of large blood vessels (giant cell arteritis) has been reported after administration of influenza vaccines, including Aujemflu. This is a rare condition that may cause a severe headache, scalp tenderness, jaw pain or visual problems (see section 4, Possible side effects). If you experience any of these symptoms, seek immediate medical attention.

### **Children**

Aujemflu is not recommended for use in children.

### **Other medicines and Aujemflu**

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription or if you have recently received any other vaccine.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this vaccine. Your doctor needs to assess the benefits and potential risks of giving you the vaccine.

### **Driving and using machines**

Aujemflu has no or negligible effect on your ability to drive and use machines. However, some of the side effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect the ability to drive and use machines. Wait until these effects have worn off before driving and using machines.

### **Aujemflu contains sodium and potassium**

This vaccine contains less than 1 mmol of sodium (23 mg) per dose, this means that it is essentially ‘sodium-free’.

This vaccine contains less than 1 mmol of potassium (39 mg) per dose, this means that it is essentially ‘potassium-free’.

## **3. How Aujemflu is given**

Your doctor, nurse or pharmacist administers the vaccine in accordance with official recommendations.

*Adults 50 years of age and older:*

One dose (1.0 ml) of the vaccine will be injected into the upper arm (deltoid muscle).

#### **4. Possible side effects**

Like all medicines, Aujemflu can cause side effects, although not everybody gets them.

##### **Very serious side effects**

Tell your doctor immediately or go to the emergency department at your nearest hospital if you experience any of the following side effects – you may need urgent medical attention or hospitalisation:

- Signs or symptoms of an allergic reaction (which may be severe) such as difficulty in breathing, dizziness, a weak and rapid pulse, skin rash
- Inflammation of large blood vessels which can cause symptoms such as severe headaches, pain or tenderness at the side of your head (temples) or on the scalp, jaw pain while eating or talking, vision problems (giant cell arteritis)

##### **Serious side effects**

Tell your doctor immediately if you experience any of the following side effects – you may need medical attention:

Rare (may affect up to 1 in 1000 people):

- Weakness of face muscles on one side of the face (Bell's palsy)

##### **Other side effects**

Other side effects which may occur with Aujemflu include those listed below.

*Adults 50 years of age and older*

The following side effects have occurred with a similar vaccine in clinical studies in adults, including the elderly:

Very common (may affect more than 1 in 10 people):

- Injection site pain
- Fatigue
- Headache
- Aching joints (arthralgia) and muscles (myalgia)

Common (may affect up to 1 in 10 people):

- Nausea
- Injection site hardness (induration) and bruising (ecchymosis)
- Fever

Rare (may affect up to 1 in 1000 people):

- Fainting (syncope)
- Dizziness
- Chills
- Injection site itching (pruritus)
- Injection site swelling

Most side effects were mild or moderate and went away within 3 days of appearing.

Elderly subjects, 65 years of age and older, generally reported fewer reactions compared to younger adults.

#### Unknown (Frequency cannot be estimated from the available data)

In addition to the side effects reported above from clinical studies, the following additional side effects have been reported with use of similar seasonal influenza vaccines:

- Temporary low blood platelet count which can result in bleeding or bruising (transient thrombocytopenia)
- Swollen lymph nodes (lymphadenopathy)
- Neurological disorders such as, severe stabbing or throbbing pain along one or more nerves (neuralgia), tingling (paraesthesia), inflammation of the nerves (neuritis), fits (convulsions), inflammation of the central nervous system (encephalomyelitis), a type of paralysis (Guillain-Barré syndrome), feeling about to faint (presyncope) and dizziness.
- Inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems (vasculitis)
- Generalised skin reactions including hives (urticaria), itchiness of the skin (pruritus), non-specific rash, severe skin rash (erythema multiforme), abnormal swelling of the skin, usually around the eyes, lips, tongue, hands or feet, due to an allergic reaction (angioedema), skin redness (erythema)
- Swelling, pain and redness at the injection site (injection site cellulitis-like reaction)
- Swelling of the lower legs or hands (peripheral swelling), extensive swelling of the vaccinated limb
- Pain in extremities, weakness of the muscles
- General weakness (asthenia), generally feeling unwell (malaise)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Aujemflu**

Keep this vaccine out of the sight and reach of children.

Do not use Aujemflu after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Discard if the vaccine has been frozen. Keep the pre-filled syringe in the original carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Aujemflu contains**

#### **- Active substance:**

The active ingredients of the vaccine are purified viral proteins (called haemagglutinin and neuraminidase).

One dose (1.0 ml) of the vaccine contains 45 micrograms of haemagglutinin from the following influenza virus strains\*:

A/Wisconsin/67/2022 (H1N1)pdm09-like strain (A/Georgia/12/2022, CVR-167) 45 micrograms HA\*\*

A/District of Columbia/27/2023 (H3N2)-like strain (A/Victoria/800/2024, CVR-289) 45 micrograms HA\*\*

B/Austria/1359417/2021-like strain (B/Singapore/WUH4618/2021, wild type) 45 micrograms HA\*\*

\*propagated in Madin Darby Canine Kidney (MDCK) cells (this is the special cell culture in which the influenza virus is grown).

\*\*haemagglutinin

- Adjuvant:

MF59C.1 is included in this vaccine as an adjuvant. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine. MF59C.1 is an adjuvant that contains squalene, polysorbate 80, sorbitan trioleate, sodium citrate and citric acid.

- Other ingredients:

The other ingredients are: sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate, and water for injections, see section 2 Aujemflu contains sodium and potassium.

### **What Aujemflu looks like and contents of the pack**

Aujemflu is a suspension for injection in a pre-filled syringe. It appears as a milky-white suspension.

It is provided in a ready-to-use syringe, containing a single dose (1.0 ml) for injection, in a pack of 1 or 10 pre-filled syringes, with or without needles.

Not all pack sizes are available.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Seqirus UK Limited  
Point, 29 Market Street  
Maidenhead, SL6 8AA  
United Kingdom

#### **Manufacturer**

Seqirus Vaccines Ltd  
Gaskill Road, Speke, Liverpool  
L24 9GR  
United Kingdom

**This leaflet was last revised in 05/2026**

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The following information is intended for healthcare professionals only:

Appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Gently shake before use. After shaking, the normal appearance of Aujemflu is a milky-white suspension.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

To use the pre-filled syringe without a needle supplied with a Luer Lock system, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Use a sterile needle of the appropriate size for intramuscular injection. Once the needle is locked in place, remove the needle protector and administer the vaccine.