

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aujemflu suspension for injection in pre-filled syringe

Adjuvanted Trivalent Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following 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**

per 1.0 ml dose

* propagated in Madin Darby Canine Kidney (MDCK) cells ** haemagglutinin.

Adjuvant MF59C.1 containing per 1.0 ml dose: squalene (19.5 mg), polysorbate 80 (2.35 mg), sorbitan trioleate (2.35 mg), sodium citrate (1.32 mg), citric acid (0.08 mg).

This vaccine complies with the World Health Organisation (WHO) recommendations (Northern Hemisphere) and EU recommendation for the 2025/2026 season.

Aujemflu may contain trace residues of beta-propiolactone, cetyltrimethylammonium bromide and polysorbate 80 which are used during the manufacturing process (see section 4.3).

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection (injection).
Milky-white suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza in adults 50 years of age and older.

Aujemflu should be used in accordance with official recommendations.

4.2 Posology and method of administration

Posology

One 1.0 ml dose.

Paediatric population

Safety and efficacy of Aujemflu in children from birth to less than 18 years has not been established. No data are available.

Method of administration

For intramuscular injection only.

The preferred injection site is the deltoid muscle of the upper arm.

The vaccine must not be injected intravascularly, subcutaneously or intradermally and must not be mixed with other vaccines in the same syringe.

For instructions on handling and disposal, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any components of the adjuvant, to any excipients listed in section 6.1, or to possible trace residues such as beta-propiolactone, cetyltrimethylammonium bromide and polysorbate 80.

A severe allergic reaction (e.g., anaphylaxis) to a previous dose of an influenza vaccine.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded.

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. However, the presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Immunocompromised patients

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza.

Limitations of vaccine effectiveness

A protective immune response may not be elicited in all vaccine recipients.

Giant cell arteritis

Giant cell arteritis (GCA) is a rare condition and has been reported in temporal relation with influenza vaccination, including two case reports after administration of Aujemflu in a clinical trial (see section 4.8). Healthcare professionals should be alert to the clinical signs and symptoms suggestive of GCA such as a severe headache, scalp tenderness, jaw pain or visual disturbances and advise vaccine recipients, especially those at increased risk of GCA (older adults, women and individuals with polymyalgia rheumatica), to seek immediate medical attention if they experience such symptoms.

Excipients with known effect

Sodium

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

Potassium

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. If Aujemflu is given at the same time as another injectable vaccine(s), the vaccine(s) should always be administered to separate limbs. It should be noted that adverse reactions may be intensified.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of Aujemflu in pregnant women.

There have been no reproductive and developmental toxicology studies with Aujemflu. Reproductive and developmental toxicology data from cell-based trivalent influenza vaccine (TIVc) and MF59 do not predict an increased risk of developmental abnormalities.

Breast-feeding

Aujemflu has not been evaluated during breast-feeding. The vaccine is not expected to be excreted in human milk and no effects on the breastfed newborn/infant are anticipated.

Fertility

No human fertility data are available. Animal data, with cell-based trivalent influenza vaccine (TIVc) and MF59, have not shown effects on female fertility. Male fertility has not been assessed in animals.

4.7 Effects on ability to drive and use machines

Aujemflu has no or negligible influence on the ability to drive and use machines. However, some of the undesirable effects mentioned under section 4.8 may affect the ability to drive or operate machinery.

4.8 Undesirable effects

Summary of the safety profile

Data with aQIVc, a quadrivalent formulation of Aujemflu, are relevant to Aujemflu because both vaccines are manufactured using the same process and have overlapping compositions.

The most commonly reported ($\geq 10\%$) adverse reactions reported in adults 50 to 64 years of age following administration of aQIVc were injection site pain (54%), fatigue (38%), headache (27%), myalgia (21%) and arthralgia (20%).

The most commonly reported ($\geq 10\%$) adverse reactions reported in adults 65 years of age and older following administration of aQIVc were injection site pain (38%), fatigue (28%), headache (17%), arthralgia (14%) and myalgia (13%).

Most solicited reactions were reported as mild or moderate in intensity and resolved within the first 3 days after vaccination.

Tabulated list of adverse reactions

The frequencies of adverse reactions are based on a clinical study (V201_03) in which 3282 adults 50 years of age and older received aQIVc.

The adverse reactions are listed according to the following MedDRA frequency convention and system organ class: Very common ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Rare ($\geq 1/10\,000$ to $< 1/1\,000$).

Table 1: Adverse reactions reported in adults 50 years of age and older

MedDRA system organ class	Very common ($\geq 1/10$)	Common ($\geq 1/100$ to $< 1/10$)	Rare ($\geq 1/10\,000$ to $< 1/1\,000$)
Nervous system disorders	Headache		Dizziness ^a , Bell's palsy ^a , syncope
Vascular disorders			Giant cell arteritis ^a
Gastrointestinal disorders		Nausea	
Musculoskeletal and connective tissue disorders	Arthralgia, myalgia		
General disorders and administration site conditions	Injection site pain, fatigue	Injection site induration, injection site erythema, fever	Chills ^a , injection site pruritus ^a , injection site swelling

^a unsolicited adverse reaction reported within 29 days of vaccination.

Description of selected adverse reactions

Giant cell arteritis

In the Phase 3 study V201_03, one serious case of giant cell arteritis (GCA) was reported in an elderly female study participant on Day 5 after vaccination with aQIVc, and one non-serious case of a relapse of GCA was reported in an elderly female participant with a known history of GCA on Day 2 after vaccination with aQIVc.

Elderly population

Elderly individuals 65 years and older generally reported fewer solicited local and systemic reactions compared to younger adults.

Adverse reactions from post-marketing experience

There is no post-marketing experience following administration of Aujemflu. However, the following post-marketing adverse events have been reported after use of seasonal influenza vaccines that are made using the same cell-based manufacturing process or contain the same MF59 adjuvant as Aujemflu (Table 2).

Table 2: Post-marketing experience reported after use of similar influenza vaccines

MedDRA system organ class	Adverse reaction¹
Blood and lymphatic system disorders	Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per mm ³), lymphadenopathy
Immune system disorders	Allergic reactions including anaphylactic shock (in rare cases), anaphylaxis
Nervous system disorders	Encephalomyelitis, Guillain-Barré Syndrome, convulsions, neuritis, neuralgia, paraesthesia, presyncope
Vascular disorders	Vasculitis which may be associated with transient renal involvement
Skin and subcutaneous tissue disorders	Generalised skin reactions including erythema multiforme, urticaria, pruritus or non-specific rash, erythema, angioedema
Musculoskeletal and connective tissue disorders:	Muscular weakness, pain in extremity
General disorders and administration site conditions	Extensive swelling of injected limb, injection site cellulitis-like reaction, peripheral swelling, asthenia, malaise

¹ Frequency not known (cannot be estimated from the available data)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There is insufficient experience on overdose with Aujemflu. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccines, influenza vaccine, ATC Code: J07BB02.

Mechanism of action

Aujemflu provides active immunisation against three influenza virus strains (two A subtypes and one B type) contained in the vaccine. It induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses. This vaccine contains the adjuvant MF59C.1 (MF59), which is designed to increase and broaden the antigen-specific immune response and to extend the duration of the immune response.

Specific levels of haemagglutination inhibition (HI) antibody titres post-vaccination with inactivated influenza vaccine have not been correlated with protection from influenza virus, but the HI antibody titres have been used as a measure of vaccine efficacy.

Antibody against one influenza virus type or subtype confers limited or no protection against another. Furthermore, antibody to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype.

Annual revaccination with the influenza vaccines is recommended because immunity declines during the year after vaccination and circulating strains of influenza virus change from year to year.

Pharmacodynamic effects

Data with aQIVc, a quadrivalent formulation of Aujemflu, are relevant to Aujemflu because both vaccines are manufactured using the same process and have overlapping compositions.

Immunogenicity

Immunogenicity of aQIVc was assessed in Study V201_03, a Phase 3, a multicentre, observer-blind, randomised study conducted in United States, Canada, United Kingdom, Germany, Denmark, Estonia, Pakistan, Philippines during the 2023-2024 Northern Hemisphere influenza season. In this study a total of 7 699 participants 50 years of age and older who were healthy or had stable comorbidities that increase their risk of complications from influenza infection were enrolled and randomised in a 3:2:2

ratio to receive aQIVc, Adjuvanted Quadrivalent Influenza Vaccine Seqirus (aQIV [egg based]) or a quadrivalent recombinant seasonal influenza vaccine comparator (QIVr). Randomisation was stratified by age group (50 to 64 years; 65 years and older), history of any influenza vaccination within the previous 3 influenza seasons and site. The mean age of the exposed participant population was 64.3 years (range 50 to 95 years) with 49.8% participants between 50 to 64 years, 39.3% between 65 to 74 years, 9.7% between 75 to 84 years and 1.2% over 85 years. The majority of participants were white (74.2%) or Asian (19.3%). Females represented 56.1% of participants and 60.5% of participants had a history of any influenza vaccination in the previous 3 influenza seasons.

Post-vaccination immunogenicity was evaluated in sera collected 28 days after vaccination.

Haemagglutination inhibition (HI) geometric mean titres (GMTs) were measured for the three vaccine groups for each vaccine antigen using cell-derived target viruses. Immunogenicity was compared by calculating the ratio of adjusted GMTs at Day 29 and the difference in seroconversion rates (SCR).

aQIVc induced an immune response that was superior to the responses induced by aQIV for all 4 strains 28 days after vaccination in adults 50 years of age and older as measured by GMT ratios and SCR differences (Table 3).

Table 3: Post-vaccination GMT and seroconversion of aQIVc compared to aQIV in participants 50 years of age and older at Day 29 by HI Assay using cell-derived target viruses

	GMT^a (95% CI)		GMT Ratio^{b, c} (97.5% CI)
Strains:	aQIVc (N=3 175)	aQIV (N=2 129)	aQIVc/aQIV
A/H1N1	319.06 (298.59, 340.94)	208.08 (193.72, 223.51)	1.53 (1.43 - 1.64)
A/H3N2	221.43 (208.45, 235.21)	181.24 (169.82, 193.44)	1.22 (1.15 – 1.30)
B/Victoria	196.93 (185.55, 209.01)	113.61 (106.55, 121.14)	1.73 (1.63 – 1.85)
B/Yamagata	101.36 (96.74, 106.20)	59.26 (56.35, 62.31)	1.71 (1.63 – 1.80)
	Seroconversion^d Rate % (95% CI)		Seroconversion Rate difference^e (97.5% CI)
Strains:	aQIVc (N=3 175)	aQIV (N=2 129)	aQIVc – aQIV

A/H1N1	75.0 (73.4, 76.5)	58.1 (56.0, 60.3)	16.8 (13.9, 19.8)
A/H3N2	66.4 (64.7, 68.0)	56.9 (54.7, 59.0)	9.5 (6.4, 12.5)
B/Victoria	59.2 (57.5, 61.0)	37.4 (35.3, 39.5)	21.9 (18.8, 24.9)
B/Yamagata	53.0 (51.2, 54.7)	28.7 (26.8, 30.7)	24.3 (21.3, 27.2)

Abbreviations GMT = Geometric mean antibody titre; CI = Confidence Interval

N = the number of vaccinated participants with available data for the immunologic endpoint listed (Per Protocol Set). ^a GMT measured at Day 29 after vaccination

^b Non-inferiority success criteria defined as the lower limit of the 97.5% CI for the Day 29 GMT ratios [aQIVc/aQIV] is ≥ 0.67 for each vaccine strain

^c Superiority success criteria defined as the lower limit of the 97.5% CI for GMT ratio [aQIVc/aQIV] is >1.0 for each vaccine strain.

^d Seroconversion was defined as pre-vaccination HI titre $<1:10$ and postvaccination HI titre $\geq 1:40$ or at least a 4-fold increase in HI from pre-vaccination HI titre $\geq 1:10$.

^e Non-inferiority success criteria defined as the lower limit of the 97.5% CI for the difference in seroconversion rates [aQIVc minus aQIV] is $\geq -10\%$ for each vaccine strain.

Non-inferiority success criteria as measured by GMT ratios and SCR differences against the second comparator, QIVr, were met for 3 out of 4 strains in the vaccines (Table 4).

Table 4: Post-vaccination GMT and seroconversion of aQIVc compared to QIVr in subjects 50 years of age and older at Day 29 by HI Assay using cell-derived target viruses

	GMT^a (95% CI)		GMT Ratio^b (97.5% CI)
Strains:	aQIVc (N=3 175)	QIVr (N=2 115)	aQIVc/QIVr
A/H1N1	319.06 (298.59, 340.94)	342.46 (318.69, 368.00)	0.93 (0.87, 1.00)
A/H3N2	221.43 (208.45, 235.21)	318.94 (298.71, 340.53)	0.69 (0.65, 0.74)
B/Victoria	196.93 (185.55, 209.01)	139.40 (130.68, 148.70)	1.41 (1.33, 1.50)
B/Yamagata	101.36 (96.74, 106.20)	76.11 (72.35, 80.06)	1.33 (1.27, 1.40)
	Seroconversion^c Rate % (95% CI)		Seroconversion Rate difference^d (97.5% CI)

Strains:	aQIVc (N=3 175)	QIVr (N=2 115)	aQIVc – QIVr
A/H1N1	75.0 (73.4, 76.5)	73.5 (71.5, 75.3)	1.5 (-1.2, 4.3)
A/H3N2	66.4 (64.7, 68.0)	73.8 (71.9, 75.7)	-7.4 (-10.3, -4.6)
B/Victoria	59.2 (57.5, 61.0)	47.6 (45.5, 49.8)	11.6 (8.5, 14.7)
B/Yamagata	53.0 (51.2, 54.7)	39.6 (37.5, 41.7)	13.4 (10.3, 16.5)

Abbreviations GMT = Geometric mean antibody titre; CI = Confidence Interval

N = the number of vaccinated participants with available data for the immunologic endpoint listed (Per Protocol Set). ^a GMT measured at Day 29 after vaccination ^b Non-inferiority success criteria defined as the lower limit of the 97.5% CI for the Day 29 GMT ratios [aQIVc/QIVr] is

≥ 0.67 for each vaccine strain

^cSeroconversion was defined as pre-vaccination HI titre <1:10 and postvaccination HI titre ≥ 1:40 or at least a 4-fold increase in HI from pre-vaccination HI titre ≥ 1:10.

^d Non-inferiority success criteria defined as the lower limit of the 97.5% CI for the difference in seroconversion rates [aQIVc minus QIVr] is ≥ -10% for each vaccine strain.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on a repeated-dose toxicity study with aQIVc. Data with aQIVc are relevant because aQIVc and Aujemflu are manufactured using the same process and have overlapping compositions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride (E508)
Magnesium chloride hexahydrate (E511)
Disodium phosphate dihydrate
(E339) Potassium dihydrogen
phosphate (E340) Water for
injections.

For the adjuvant, see section 2

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

Do not freeze. Discard the vaccine if it has been frozen.

Keep the pre-filled syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

1.0 ml suspension in pre-filled syringe (type I glass) with plunger-stopper (bromobutyl rubber) presented with or without needle.

Packs of 1 or 10 pre-filled syringes. Each pre-filled syringe contains 1 dose of 1.0 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

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

Visually inspect the content of each pre-filled syringe for particulate matter and/or variation in appearance prior to administration. If either condition is observed, do not administer the vaccine.

To use the pre-filled syringe 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.

Any unused vaccine and waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 47991/0020

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

04/06/2026

10 DATE OF REVISION OF THE TEXT

04/06/2026