PRESCRIBING INFORMATION – UNITED KINGDOM

Please consult the Summary of Product Characteristics (SPC) before prescribing

Aujemflu▼ Adjuvanted trivalent influenza vaccine (surface antigen, inactivated, prepared in cell cultures)

Indication: Prophylaxis of influenza in adults 50 years of age and older. **Presentation:** Each 1.0 ml dose of Adjuvanted Trivalent Influenza Vaccine (Aujemflu) contains 45 micrograms of each of the three strains that comply with the World Health Organisation trivalent vaccine recommendations (Northern Hemisphere) with adjuvant MF59C.1 (19.75 mg squalene, 2.35 mg polysorbate 80, 2.35 mg sorbitan trioleate, 1.32 mg sodium citrate, 0.08 mg citric acid). **Dosage and Administration:** A single 1.0 ml dose by intramuscular injection only (preferred site is the deltoid muscle of the upper arm). **Contraindications:** Hypersensitivity to the active substances, to any components of the adjuvant, to any excipients (sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate, water for injection), or to possible trace residues (beta-propiolactone, cetyltrimethylammonium bromide, polysorbate 80). A severe allergic reaction (e.g., anaphylaxis) to a previous dose of an influenza vaccine. **Warnings and Precautions:** 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. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. 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. 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. 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. Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient to prevent influenza. A protective immune response may not be elicited in all vaccine recipients.

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. 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.

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

Interactions: Concomitant administration of Aujemflu with other vaccines has not been studied in trials conducted by Seqirus. 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 the adverse reactions may be intensified.

Pregnancy and Lactation: There are no data on the use of Aujemflu in pregnant or breastfeeding women. No reproductive and developmental toxicity studies have been conducted. 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. **Effects on Ability to Drive and Use Machines:** Aujemflu has no or negligible influence on the ability to drive and use machines.

Side effects: The most commonly reported (≥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 (≥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. **Adverse reactions reported following vaccination in clinical trials**, the most common reactions (≥1/10) were myalgia, arthralgia, headache, injection-site pain, and fatigue. Commonly reported reactions (≥1/100 to <1/10) were nausea, injection site induration, injection site erythema, fever. Rare reported reactions (≥1/10000 to <1/1000) dizziness, Bell's palsy, syncope. **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. There is no post-marketing experience following administration of Aujemflu. **Elderly population:** Elderly individuals 65 years and older generally reported fewer solicited local and systemic reactions compared to younger adults. **Overdose:** There is insufficient experience on overdose with Aujemflu. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended. **Legal category:** POM.

Package Quantities: Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Holder:** Seqirus UK Ltd., Point, 29 Market Street, Maidenhead SL6 8AA, United Kingdom. **Market Authorisation Number:** PL 47991/0020 **Basic NHS Cost:** £22 per 1.0ml pre-filled syringe. £220 per 10-pack.

For full prescribing information and full details of side effects, warnings and precautions, please see the Summary of Product Characteristics.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events relating to CSL Seqirus products should also be reported to Seqirus UK Limited on 01748 828816

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