PRESCRIBING INFORMATION – UNITED KINGDOM

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

Adjuvanted Trivalent Influenza Vaccine ▼ (Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe

Indication: Prophylaxis of influenza in adults (50 years of age and older). **Presentation:** Each 0.5 ml dose of Adjuvanted Trivalent Influenza Vaccine (aTIV) contains 15 micrograms of each of the three strains that comply with the World Health Organisation trivalent vaccine recommendations (Northern Hemisphere) with adjuvant MF59C.1 (9.75 mg squalene, 1.175 mg polysorbate 80, 1.175 mg sorbitan trioleate, 0.66 mg sodium citrate, 0.04 mg citric acid). **Dosage and Administration:** A single 0.5 ml dose by intramuscular injection only (preferred site is the deltoid muscle of the upper arm). **Contraindications:** Hypersensitivity to the active substances, components of the adjuvant, excipients (sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate), or to possible trace residues (ovalbumin, kanamycin, neomycin sulphate, formaldehyde , cetyltrimethylammonium bromide, hydrocortisone). A severe allergic reaction (e.g. anaphylaxis) to previous influenza vaccination. **Warnings and Precautions:** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. The vaccine must not be injected intravenously, subcutaneously or intradermally and must not be mixed with other vaccines in the same syringe. Vaccination should be postponed in patients with febrile illness until the fever is resolved. Caution when administering to individuals with thrombocytopenia or bleeding disorder since bleeding may occur following intramuscular administration. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. Ensure procedures are in place to avoid injury from faints. 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. **Interactions:** Concomitant administration of aTIV with other vaccines has not been studied in trials conducted by Seqirus. However, data supports co-administration with COVID vaccines showing the antibody responses are unaffected and the reactogenicity profile is acceptable. If it is to be used at the same time as another vaccine, it should be administered at separate injection sites and preferably on different limbs. It should be noted that the adverse reactions may be intensified. **Pregnancy and Lactation:** This vaccine is for use in adults 50 years and older. It is not to be used in women who are, or may be, pregnant or breast-feeding. **Effects on Ability to Drive and Use Machines:** No or negligible influence on the ability to drive and use machines. **Side effects:** Adverse reactions reported following vaccination in clinical trials and post marketing surveillance in adults 50 years of age and older showed the most common reactions (≥1/10) were myalgia, arthralgia, headache, injection-site pain, and fatigue. Commonly reported reactions (≥1/100 to <1/10) were loss of appetite, nausea, diarrhoea, ecchymosis, chills, erythema, induration, influenza-like illness and fever (≥38°C). Uncommon reactions (≥1/1000 to <1/100) included vomiting and lymphadenopathy. The following adverse events (frequency not known) were reported from post-marketing surveillance for aQIV, and/or for Adjuvanted Trivalent Influenza Vaccine which is relevant because both vaccines are manufactured using the same process and have overlapping compositions: thrombocytopenia (some very rare cases were severe with platelet counts less than 5,000 per mm^3), extensive swelling of injected limb lasting more than 1 week, injection-site cellulitis-like reaction, asthenia, malaise, pyrexia, allergic reactions including anaphylactic shock (in rare cases), anaphylaxis, muscular weakness, pain in extremity, encephalomyelitis, Guillain-Barré syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, presyncope, generalised skin reactions (erythema multiforme, erythema, urticaria, pruritus, non-specific rash, angioedema), vasculitis that may be associated with transient renal involvement. **Overdose:** Overdosage is unlikely to have any untoward effect. **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:** PLGB 47991/0014 **Basic NHS Cost:** £17.55 per 0.5ml pre-filled syringe. £175.50 Per 10-pack.

For full prescribing information and details of other side effects, 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