PRESCRIBING INFORMATION (GREAT BRITAIN)

Adjuvanted quadrivalent influenza vaccine ▼ (surface antigen, inactivated) Seqirus, suspension for injection in pre-filled syringe. **Presentation:** Each 0.5 ml dose of adjuvanted quadrivalent influenza vaccine (aQIV) contains 15 micrograms of each of the four strains that comply with the World Health Organization quadrivalent 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). **Indications:** Prophylaxis of influenza in the elderly (65 years of age and older). **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. Do not inject intravenously, subcutaneously or intradermally. aQIV must not be mixed with other vaccines in the same syringe. Postpone vaccination in patients with febrile illness until 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:** If aQIV is to be used at the same time as another vaccine, it should be administered at separate injection sites and preferably on different limbs. Adverse reactions may be intensified by any co-administration. Data assessed by the MHRA supports concomitant administration of Fluad (trivalent formulation) with COVID-19 mRNA Vaccine BNT162b2 (Pfizer/BioNTech) and COVID-19 Vaccine AstraZeneca. The data show that the antibody responses are unaffected and that the reactogenicity profile is acceptable. **Pregnancy and Lactation:** This vaccine is for use in elderly adults 65 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:** The most common reactions (≥1/10) are headache, injection-site pain, and fatigue. Commonly reported reactions (≥1/100 to <1/10) are loss of appetite, nausea, diarrhoea, myalgia, arthralgia, ecchymosis, chills, erythema, induration, and influenza-like illness. Uncommon reactions (≥1/1000 to <1/100) include vomiting and fever (≥38°C). In addition to the adverse reactions observed during clinical trials, the following adverse events were reported from post-marketing surveillance in individuals 65 years of age and older for Fluad Tetra, and/or for Fluad (trivalent formulation), which is relevant because both vaccines are manufactured using the same process and have overlapping compositions thrombocytopenia, lymphadenopathy, extensive swelling of injected limb, injection-site cellulitis-like reaction, Injection side swelling, peripheral swelling, 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, dizziness, generalised skin reactions (erythema multiforme, erythema, urticaria, pruritus, non-specific rash, angioedema), vasculitis that may be associated with transient renal involvement. **Overdose:** Overdose is unlikely to have any untoward effect.

Legal Category: POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Number:** PLGB 47991/0007. **Basic NHS Cost:** £13.50 per 0.5 ml pre-filled syringe, £135.00 per 10 pack. **Marketing Authorisation Holder:** Seqirus UK Ltd., Point, 29 Market Street, Maidenhead SL6 8AA, United Kingdom.

For full prescribing information and details of other side effects, please see the Summary of Product Characteristics:
www.medicines.org.uk/emc/product/12881/

GBR-AQIV-23-0010 Date of preparation: May 2023

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.