PRESCRIBING INFORMATION

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 acute 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:** No clinical data on concomitant administration with other vaccines are available. If aQIV is to be used at the same time as another vaccine, it should be administered at separate sites and preferably on different limbs. Adverse reactions may be intensified by any co-administration. **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). No post-marketing data is currently available for aQIV, however the post-marketing experience with Fluad (trivalent formulation) is relevant to aQIV as both vaccines are manufactured using the same process and have overlapping compositions. Adverse reactions reported from post-marketing surveillance with Fluad include thrombocytopenia, lymphadenopathy, extensive swelling of injected limb lasting more than one week, injection-site cellulitis-like reaction, allergic reactions including anaphylactic shock (in rare cases), anaphylaxis, angioedema, muscular weakness, nervous system disorders (encephalomyelitis, Guillain-Barré syndrome, convulsions, neuritis, neuralgia, paraesthesia), generalised skin reactions (erythema multiforme, urticaria, pruritus or non-specific rash), 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 at www.medicines.org.uk/emc.

GBR-AQIV-21-0001 Date of preparation: September 2021

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