

PRESCRIBING INFORMATION

Adjuvanted Trivalent Influenza Vaccine (aTIV) (surface antigen, inactivated)

suspension for injection in pre-filled syringe. **Presentation:** Each 0.5ml of adjuvanted Trivalent Influenza Vaccine (aTIV) contains 15 micrograms of each of three purified virus strains that comply with the World Health Organization trivalent vaccine recommendations (Northern Hemisphere) for the current season, with adjuvant MF59C.1 (9.75mg squalene, 1.175mg polysorbate 80, 1.175mg sorbitan trioleate, 0.66mg sodium citrate, 0.04mg citric acid, water). **Indications:** Active immunisation against influenza in the elderly (65 years of age and over), especially for those with an increased risk of associated complications. **Dosage and Administration:** Adults aged 65 years and over: single 0.5ml dose by intramuscular injection into the deltoid muscle using a 1-inch needle. **Contraindications:** Hypersensitivity to the active substances, components of the adjuvant, excipients, to chicken or egg proteins (such as ovalbumin), kanamycin, neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB), hydrocortisone, or in anyone who has had an anaphylactoid reaction to previous influenza vaccination. Immunisation shall be postponed in patients with febrile illness or acute infection. **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 be readily available in case of an anaphylactic event following administration. Do not inject intravascularly or subcutaneously. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions, 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. It is important that procedures are in place to avoid injury from faints. Endogenous or iatrogenic immunosuppression may result in insufficient antibody response. *Latex-sensitive individuals:* Although no natural rubber

latex is detected in the syringe tip cap, the safe use of aTIV in latex-sensitive individuals has not been established.

Interactions: No clinical data on concomitant administration with other vaccines are available. If aTIV needs to be used at the same time as another vaccine, immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified. **Pregnancy and Lactation:** Not applicable. **Effects on Ability to Drive and Use Machines:** aTIV has no or negligible influence on the ability to drive and use machines. **Side Effects:** The most common reactions are headache, myalgia, injection site pain and tenderness, fatigue, nausea, diarrhoea, vomiting, sweating, arthralgia, fever, malaise, and shivering; local reactions include redness, swelling, ecchymosis, and induration. Uncommon reactions include rash. The following have been reported post-marketing: thrombocytopenia, lymphadenopathy, asthenia, influenza-like illness, extensive swelling of injected limb, injection-site cellulitis-like reaction, allergic reactions including anaphylactic shock (in rare cases), anaphylaxis, angioedema, generalised skin reactions including erythema multiforme, urticaria, pruritus or non-specific rash, vasculitis which may be associated with transient renal involvement, and neurological disorders such as encephalomyelitis, Guillain-Barré syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, and presyncope. **Overdose:** Overdosage is unlikely to have any untoward effect.

Legal Category: POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Number:** UK: PL 47991/0001. **Basic NHS Cost:** £9.79 per 0.5ml pre-filled syringe, £97.90 per 10 pack. **Marketing Authorisation Holder:** Seqirus UK Limited, Level 3, 29 Market Street, Maidenhead, SL6 8AA, UK

For full prescribing information and details of other side effects see the Summary of Product Characteristics at www.medicines.org.uk/emc

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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 Seqirus products should also be reported to Seqirus UK Limited on 01748 828816.