

References

1. FLUAD® TETRA Summary of Product Characteristics 2020. 2. Joint Committee on Vaccination and Immunisation (JCVI). Advice on influenza vaccines for 2021/22. November 2020. Available from: <https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo/file/737845224649>. [Accessed Nov 2020].

PRESCRIBING INFORMATION

Fluad® Tetra ▼, Adjuvanted quadrivalent influenza vaccine (surface antigen, inactivated),

suspension for injection in pre-filled syringe. **Presentation:** Each 0.5 ml dose 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. Fluad Tetra 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 Fluad Tetra 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 ($\geq 1/10$) are headache, injection-site pain, and fatigue. Commonly reported reactions ($\geq 1/100$ to $< 1/10$) are loss of appetite, nausea, diarrhoea, myalgia, arthralgia, ecchymosis, chills, erythema, induration, and influenza-like illness. Uncommon reactions ($\geq 1/1000$ to $< 1/100$) include vomiting and fever ($\geq 38^\circ\text{C}$). No post-marketing data is currently available for Fluad Tetra, however the post-marketing experience with Fluad (trivalent formulation) is relevant to Fluad Tetra 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 Numbers:** EU/1/20/1433/001, EU/1/20/1433/002, EU/1/20/1433/003, EU/1/20/1433/004. **Basic NHS Cost:** £11.88 per 0.5 ml pre-filled syringe, £118.80 per 10 pack. **Marketing Authorisation Holder:** Seqirus Netherlands B.V., Paasheувelweg 28, 1105BJ, Amsterdam, Netherlands.

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

UK/FLUT/0720/0002a(1).

Date of preparation: November 2020.

Fluad® Tetra is a registered trademark of Seqirus UK Limited.

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.