

PRESCRIBING INFORMATION

Flucelvax® Tetra ▼ **Influenza vaccine (surface antigen, inactivated, prepared in cell cultures),**

suspension for injection in pre-filled syringe. **Presentation:** Each 0.5ml of Flucelvax® Tetra contains 15 micrograms of each of four purified virus strains propagated in Madin Darby Canine Kidney (MDCK) cells that comply with the World Health Organization quadrivalent vaccine recommendations (Northern Hemisphere) for the current season. **Indications:** Prophylaxis of influenza in adults and children from 9 years of age. **Dosage and Administration:** Adults and children aged 9 years and over: single 0.5ml dose by intramuscular injection in the deltoid muscle of the upper arm. The vaccine must not be injected intravenously, subcutaneously, or intradermally. **Contraindications:** Hypersensitivity to the active substance, to any of the excipients (sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate), or to possible trace residues (beta-propiolactone, cetyltrimethylammonium bromide, and polysorbate 80). **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. Vaccination should be postponed in patients with acute febrile illness until fever is resolved. As with all injectable vaccines, Flucelvax® Tetra must be administered with caution to individuals with thrombocytopenia or a bleeding disorder since bleeding may occur following intramuscular administration. Syncope (fainting) can occur following or 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. **Interactions:** No clinical data on concomitant administration with other vaccines are available. Based on

clinical experience with cell-based trivalent influenza vaccine (TIVc), Flucelvax® Tetra can be given at the same time as other vaccines. **Pregnancy and Lactation:** There are limited data from the use of Flucelvax® Tetra in pregnant women. However, inactivated influenza vaccines can be used at all stages of pregnancy. It is unknown whether Flucelvax® Tetra is excreted in human milk. No effects on breast-fed newborn/infant are anticipated. Flucelvax® Tetra may be used during lactation. **Effects on Ability to Drive and Use Machines:** Flucelvax® Tetra has no or negligible influence on the ability to drive and use machines. **Side Effects:** The most common reactions are injection site pain, headache, fatigue, myalgia, erythema, and induration. Commonly reported adverse reactions include loss of appetite, nausea, diarrhoea, vomiting, arthralgia, ecchymosis, and chills. Uncommon reactions include fever. The following have been reported post-marketing: extensive swelling of injected limb, allergic reactions (including anaphylactic shock), paraesthesia, and generalised skin reactions (including pruritus, urticaria, or non-specific rash). Paediatric subjects generally reported higher rates of local and systemic reactions compared to adults aged 18 years and over. **Overdose:** There are no data for overdose with Flucelvax® Tetra.

Legal Category: POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Numbers:** EU/1/18/1326/001, EU/1/18/1326/002, EU/1/18/1326/003, EU/1/18/1326/004. **Basic NHS Cost:** £9.94 per 0.5ml pre-filled syringe, £99.40 per 10-pack. **Marketing Authorisation Holder:** Seqirus Netherlands B.V., Paasheuvelweg 28, 1105BJ, Amsterdam, Netherlands.

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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Flucelvax® 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.