PRESCRIBING INFORMATION – UNITED KINGDOM

Please consult the Summary of Product Characteristics (SPC) before prescribing

Cell-based Trivalent Influenza Vaccine ▼(Surface Antigen, Inactivated) Seqirus suspension for injection in pre-filled syringe

Indication: Prophylaxis of influenza in adults and children from 6 months of age. **Presentation:** Each 0.5 ml of cell-based trivalent influenza vaccine (TIVc) contains 15 micrograms of each of three purified virus strains propagated in Madin Darby Canine Kidney (MDCK) cells that comply with the World Health Organization trivalent vaccine recommendations (Northern Hemisphere) for the current season. **Dosage and Administration:** Adults and children aged 6 months and over should receive a single 0.5 ml dose, children aged 6 months to less than 9 years of age who have not been previously vaccinated against influenza, should receive two doses at least 4 weeks apart. For intramuscular injection only. The preferred site for injection is the deltoid muscle of the upper arm. Young children with insufficient deltoid mass should be vaccinated in the anterolateral aspect of the thigh. **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. Do not inject intravenously, subcutaneously, or intradermally and do not mix with other vaccines in the same syringe. Vaccination should be postponed in patients with febrile illness until fever is resolved. As with all injectable vaccines, TIVc 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. A protective immune response may not be elicited in all vaccine recipients**. Interactions:** TIVc can be given at the same time as other vaccines, including COVID vaccines. If TIVc is used at the same time as another vaccine, it should be administered at separate injection sites and preferably on different limbs. It should be noted that the adverse reactions may be intensified. **Pregnancy and Lactation:** Inactivated influenza vaccines, such as TIVc, can be given in any stage of pregnancy. Larger safety datasets are available on vaccine use during the second or third trimester, compared with the first trimester; however, data from a prospective pregnancy exposure registry in women vaccinated with Cell-based Quadrivalent Influenza Vaccine Seqirus during all stages of pregnancy, and worldwide use of influenza vaccines do not indicate any adverse foetal, newborn, pregnancy and maternal outcomes attributable to the vaccine. It is unknown whether the vaccine is excreted in human milk. No effects on breast fed newborn/infant are anticipated. TIVc may be given during lactation. **Effects on Ability to Drive and Use Machines:** TIVc has no or negligible influence on the ability to drive and use machines. **Side effects: In children aged 6months to <6 years**, very common reported adverse events (≥1/10) were: diarrhoea, injection site tenderness, injection site erythema, injection site induration, injection site ecchymosis, sleepiness, irritability, change in eating habits, and fever (≥38° C) and common reported adverse events (≥1/100 to <1/10) were: vomiting, chills/shivering. **In children aged 6 years to <18 years**, very common adverse events (≥1/10) were: loss of appetite, headache, myalgia, Injection site pain, injection site erythema, injection site induration, injection site ecchymosis, fatigue and common reported adverse events (≥1/100 to <1/10) were: nausea, arthralgia, chills/shivering and fever (≥38° C). **In adults aged 18 years and older,** very common reported adverse events (≥1/10) were headache, myalgia, Injection site pain, fatigue, injection site erythema, injection site induration. Other commonly reported adverse reactions in adults (≥1/100 to <1/10) were loss of appetite, nausea, vomiting, diarrhoea, arthralgia, chills and injection site ecchymosis. **The following have been reported in post-marketing surveillance in adults aged 18 years and older**: extensive swelling of injected limb, allergic reactions (including anaphylactic shock), paraesthesia, generalised skin reactions (including pruritus, urticaria, or non-specific rash), and Guillain-Barre Syndrome. Paediatric subjects generally reported higher rates of local and systemic reactions compared to adults aged 18 years and over. The incidence of adverse reactions following the second dose in children was similar or slightly lower to that observed after the first dose. **Overdose**: There are no data for overdose with TIVc. **Legal category:** POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Holder:** Seqirus UK Ltd., Point, 29 Market Street, Maidenhead SL6 8AA, United Kingdom. **Market Authorisation Number:** PLGB 47991/0015 **Basic NHS Cost:** £17.55 per 0.5ml pre-filled syringe. £175.50 Per 10-pack.

For full prescribing information and full details of side effects, warnings and precautions, please see the Summary of Product Characteristics.

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