PRESCRIBING INFORMATION (GREAT BRITAIN)

Cell-based quadrivalent influenza vaccine ▼ (surface antigen, inactivated) Seqirus, suspension for injection in pre-filled syringe. **Presentation:** Each 0.5 ml of cell-based quadrivalent influenza vaccine (QIVc) 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 6 months of age. **Dosage and Administration:** Adults and children aged 9 years 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 a second dose 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. QIVc must not be mixed 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, QIVc 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:** If QIVc is to be used at the same time as another vaccine, it should be administered at separate injection sites and preferably on different limbs. Adverse reactions may be intensified by any co-administration. Data assessed by the MHRA supports concomitant administration of QIVc with COVID-19 mRNA Vaccine BNT162b2 (Pfizer/BioNTech) and COVID-19 Vaccine AstraZeneca. The data show that the antibody responses are unaffected and that the reactogenicity profile is acceptable. **Pregnancy and Lactation:** Inactivated influenza vaccines, such as QIVc, 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. Data from worldwide use of influenza vaccines do not indicate any adverse foetal or maternal outcomes attributable to the vaccine. **Effects on Ability to Drive and Use Machines:** QIVc has no or negligible influence on the ability to drive and use machines. **Side Effects:** The most common reactions (≥1/10) are injection site pain, erythema, ecchymosis, induration, headache, fatigue, myalgia, loss of appetite. Additionally, injection site tenderness, irritability, sleepiness, diarrhoea and change in eating habits were reported in children 6 months to <6 years. Commonly reported adverse reactions (≥1/100 to <1/10) include nausea, vomiting, diarrhoea, arthralgia, chills/shivering and fever (≥38°C). Vomiting in the elderly, and fever in adults and elderly were uncommon. The following have been reported post-marketing: 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. **Overdose:** There are no data for overdose with QIVc.

Legal Category: POM. **Package Quantities:** Packs of 1 or 10 pre-filled syringes. **Marketing Authorisation Number:** PLGB 47991/0006. **Basic NHS Cost:** £12.50 per 0.5ml pre-filled syringe, £125.00 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 see the Summary of Product Characteristics: www.medicines.org.uk/emc/product/12882

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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.