

Prescribing Information – Refer to SmPC before prescribing

Fluarix Tetra Influenza vaccine (inactivated, split virion). **Indication:** active immunisation of adults and children from 6 months of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine. **Dosage and administration:** *Adults and children aged ≥6 months:* 0.5 ml for intramuscular injection. *Children aged 6 months to <9 years:* who have not previously been vaccinated against influenza, a second dose should be given after an interval of at least 4 weeks. **Adverse reactions:** See SmPC for full details. *6 to <36 months:* Very common: Loss of appetite, irritability, drowsiness, injection site pain and redness. Common: Fever ($\geq 38.0^{\circ}\text{C}$) and injection site swelling. *3 to <6 years:* Very common: Irritability, injection site pain, redness and swelling. Common: Loss of appetite, drowsiness, fever ($\geq 38.0^{\circ}\text{C}$) and injection site induration. *6 to <18 years:* Very common: Myalgia, fatigue, injection site pain, redness and swelling. Common: Headache, gastrointestinal symptoms, arthralgia, fever ($\geq 38.0^{\circ}\text{C}$), shivering and injection site induration. *Adults:* Very common: Myalgia, injection site pain and fatigue. Common: Headache, gastrointestinal symptoms, sweating, arthralgia, injection site redness, injection site swelling, shivering, fever and injection site induration. Rare: Transient lymphadenopathy, Guillain Barré syndrome, acute disseminated encephalomyelitis, anaphylaxis and angioedema. **Contraindications:** hypersensitivity to the active substances or excipients or to any component that may be present as traces such as eggs, formaldehyde, gentamicin sulphate and sodium deoxycholate. Postpone immunisation in patients with febrile illness or acute infection. **Special warnings and precautions for use:** Fluarix Tetra should under no circumstances be administered intravascularly. Fluarix Tetra should be given with caution to individuals with thrombocytopenia. **Pregnancy:** can be used in all stages of pregnancy and during breastfeeding. **Legal category:** POM. **Presentation and Basic NHS cost:** *Fluarix Tetra* 0.5 ml pre-filled syringe. 10 = £99.40, 1=£9.94. **MA No.** PL 10592/0302. **MAH:** SmithKline Beecham Limited trading as GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex, TW8 9GS. **Further information** is available from the GSK Customer Contact Centre: customercontactuk@gsk.com; Freephone 0800 221 441. **Fluarix Tetra** is a trademark of the GlaxoSmithKline group of companies. **Date of preparation:** March 2020. Ref: PI-0507 (V4.0)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441