PRESCRIBING INFORMATION

▼INFLUVAC SUB-UNIT TETRA AND INFLUENZA VACCINE TETRA MYL

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Indication: Prophylaxis of influenza in adults and children from 6 months of age especially those who run an increased risk of associated complications. The use of Influenza vaccines should be based on official recommendations.

Presentation: Influenza vaccine (surface antigen, inactivated) containing the purified haemagglutinin and neuraminidase antigens prepared from the A and B influenza virus strains recommended by WHO.

Dosage and administration: Adults and Children from 6 months to 17 years of age: 0.5 ml.

Children less than 9 years of age, without previous exposure: 4 weeks interval needed if a require second dose.

Children less than 6 months of age: The safety and efficacy of Influvac sub-unit Tetra and Influenza Vaccine Tetra MYL in children have not been established.

Immunisation should be carried out by intramuscular or deep subcutaneous injection. The preferred sites for intramuscular injection are the anterolateral aspect of the thigh in children 6 months – 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

Contraindications: Hypersensitivity to active ingredients or excipients (see SPC) and to any components that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin. Postpone immunisation in patients with febrile illness or acute infection.

Warning and precautions: Appropriate medical treatment and supervision should be available in case of an anaphylactic event. Not to be administered intravascularly.

Caution to be taken for individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to such individuals.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions 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 disturbances, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

This vaccine is intended to provide protection against those strains of virus from which vaccine is prepared and to closely related strains.

Antibody response may be insufficient in immunosuppressed patients or those receiving immunosuppressive treatment. Interference with serological testing (see SPC).

Interaction with other medicinal products: Influvac sub-unit Tetra or Influenza Vaccine Tetra MYL may be given at the same time as other vaccines, but separate limbs should be used. Following influenza vaccination, false positive results in serology tests using the ELISA method to detect HIV1, Hepatitis C and HTLV1 have been seen.

Fertility, pregnancy, and lactation:

Pregnancy: Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

Breastfeeding: May be given during breastfeeding. *Fertility:* No fertility data are available.

Effects on ability to drive and use machines: The vaccines have no or negligible influence on the ability to drive or use machines.

Undesirable effects:

Adults and Elderly: Very common: Headache, fatigue, local reaction: pain. Common: Sweating, myalgia, arthralgia, malaise, shivering, local reactions: redness, swelling, ecchymosis, induration. Uncommon: Fever. Side effects for which frequency cannot be estimated, please refer to SmPC.

Children (6 months to 17 years): Very common: Headache, drowsiness, sweating, appetite loss, nausea, abdominal pain, diarrhoea, vomiting, irritability, fussiness, myalgia, fatigue, fever, malaise, local reactions: pain, redness, swelling, induration. Common: Arthralgia, shivering, local reaction: ecchymosis. Side effects for which frequency cannot be estimated, please refer to SmPC.

Legal Category: POM

Marketing Authorisation Number and Basic NHS Price:

Influvac sub-unit Tetra suspension for injection in pre-filled syringe: PL 46302/0055; 1 x 0.5 ml pack for £9.94 and 10 x 0.5 ml pack for £99.40.

Influenza vaccine Tetra Myl suspension for injection in pre-filled syringe: PL 46302/0056; 1 x 0.5 ml pack for £8.00 and 10 x 0.5 ml pack for £80.00.

MAH: Mylan Products Ltd. Further information is available on request from: Mylan Products Ltd., Station Close, Potters Bar, Herts, EN6 1LT. Tel. 01707 853000

Date of Revision of Prescribing Information: 12 July 2021

Veeva Reference: INF-2021-0154

The SmPC for this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm and from Mylan Medical Information, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, phone no. 01707 853000, Email: info.uk@viatris.com

Reporting of Adverse Reactions

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. It allows continued monitoring of the benefit/risk balance of the medicinal product. Please continue to report suspected adverse reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme.

It is easiest and quickest to report adverse drug reactions online via the Yellow Card website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing yellowcard@mhra.gov.uk, at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789, or by downloading and printing a form from the Yellow Card section of the MHRA website.

You can also report adverse reactions direct to the marketing authorisation holder at pv.uk@viatris.com.