INFLUVAC SUB-UNIT, IMUVAC AND INFLUENZA VACCINE: PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics for full information.

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.
Indication: Prophylaxis of influenza in adults and children from 6 months of age.
Dosage and Administration: Adults and children from 36 months: 0.5 ml.
Children from 6-35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given.
The dose given should be in accordance with existing national recommendations.
Children not previously vaccinated require a second dose after an interval of at least 4 weeks.
Children less than 6 months: the safety and efficacy in children less than 6 months have not been established. No data are available.
Immunisation should be by intramuscular or deep subcutaneous injection.
Contraindications, Warnings, Precautions etc:
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.
Warnings/Precautions: Appropriate medical treatment and supervision should be available in case of an anaphylactic event.
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.
Not to be administered intravascularly. Antibody response may be insufficient in immunosuppressed patients or those receiving immunosuppressive treatment. Interference with serological testing (see SPC).
Drug Interactions: Influvac sub-unit, Imuvac or Influenza vaccine may be given at the same time as other vaccines, but separate limbs should be used. Following influenza vaccination, false positive results using the ELISA method to detect HIV1, Hepatitis C and HTLV1 antibodies have been seen. Immunological response may be reduced in patients on immunosuppressant treatment.
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.
Ability to Drive and Operate Machinery: The vaccines have no or negligible influence on the ability to drive or use machines.
Side-effects: Headache, sweating, myalgia, arthralgia, fever, malaise, shivering, fatigue.
Local reactions: redness, swelling, pain, ecchymosis, induration. Transient thrombocytopenia, transient lymphadenopathy, allergic reactions in rare cases leading to shock, angioedema. Neuralgia, paraesthesia, febrile convulsions, neurological disorders such as encephalomyelitis, neuritis and Guillain Barré syndrome. Vasculitis associated in rare cases with transient renal involvement. Generalised skin reactions e.g. pruritus, urticaria, rash.

Marketing Authorisation Holder: Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK.

PL numbers:	*Influvac sub-unit*	PL 46302/0041
	Imuvac	PL 46302/0039
	Influenza vaccine	PL 46302/0040

Basic NHS price:
Influvac sub-unit 1 x 0.5 ml and 10 x 0.5 ml syringe packs. Basic NHS price £5.22 and £52.20.
Imuvac 1 x 0.5 ml and 10 x 0.5 ml syringe packs. Basic NHS price £6.59 and £65.90.
Influenza vaccine 1 x 0.5 ml and 10 x 0.5 ml syringe packs. Basic NHS price £6.59 and £65.90

Legal Category: POM
Further Information is available from: Mylan UK Healthcare Ltd., 20 Station Close, Potters Bar, EN6 1TL, UK.

Date of last review: 13 July 2017

▼INFLUVAC SUB-UNIT TETRA AND INFLUENZA VACCINE TETRA MYL: PRESCRIBING INFORMATION

Refer to the Summary of Product Characteristics for full information.

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.
Indication: Prophylaxis of influenza in adults only (18 years of age and older). The use of Influenza vaccines should be based on official recommendations.
Dosage and Administration: Adults: 0.5 ml.
Children and adolescents: 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.
Contraindications, Warnings, Precautions etc:
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.
Warnings/Precautions: Appropriate medical treatment and supervision should be available in case of an anaphylactic event.
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.
Not to be administered intravascularly. Antibody response may be insufficient in immunosuppressed patients or those receiving immunosuppressive treatment. Interference with serological testing (see SPC).
Drug Interactions: 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.
Ability to Drive and Operate Machinery: The vaccines have no or negligible influence on the ability to drive or use machines.
Side-effects: Headache, fatigue, local reaction: pain, sweating, myalgia, arthralgia, malaise, shivering, local reactions: redness, swelling, ecchymosis, induration, fever. Transient thrombocytopenia, transient lymphadenopathy, allergic reactions, in rare cases leading to shock, angioedema. Neuralgia, paraesthesia, febrile convulsions, neurological disorders such as encephalomyelitis, neuritis and Guillain Barré syndrome. Vasculitis associated in rare cases with transient renal involvement. Generalised skin reactions including pruritus, urticaria or non-specific rash.

Marketing Authorisation Holder: Mylan Products Ltd., 20 Station Close, Potters Bar, Herts, EN6 1TL, UK.
PL numbers: *Influvac sub-unit Tetra* PL 46302/0055
Influenza vaccine Tetra MYL PL 46302/0056
Basic NHS price:
Influvac sub-unit Tetra 1 x 0.5 ml and 10 x 0.5 ml syringe packs. Basic NHS price £9.94 and £99.40.
Influenza vaccine Tetra MYL 1 x 0.5 ml and 10 x 0.5 ml syringe packs. Basic NHS price £8.00 and £80.00

Legal Category: POM
Further Information is available from: Mylan UK Healthcare Ltd., 20 Station Close, Potters Bar, EN6 1TL, UK.

Date first prepared: 06 June 2018

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard **or search for MHRA Yellow Card in the Google Play or Apple App Store.**

Adverse events should also be reported to ukpharmacovigilance@mylan.com