INFLUVAC SUB-UNIT AND IMUVAC VACCINES: PRESCRIBING 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. 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 or Imuvac 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 vaccine has 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: BGP Products Ltd., Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, SL6 4XE, UK.

PL numbers:	*Influvac sub-unit*	PL 43900/0044
	Imuvac	PL 43900/0042

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.

Legal Category: POM
Further Information is available from: BGP Products Ltd., Building Q1, Quantum House, 60 Norden Road, Maidenhead, SL6 4AY, UK.

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