

VAXIGRIP[®] JUNIOR

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION) BP

PRODUCT INFORMATION

COMPOSITION

Inactivated Influenza Vaccine (Split Virion) BP

DESCRIPTION

A purified, inactivated, split vaccine, each 0.25 mL of which contains antigens representative of the following types:

A/New Caledonia/20/99 (H1N1)-like strain (A/New Caledonia /20/99 IVR-116) 7.5ug haemagglutinin, A/Wisconsin/67/2005 (H3N2)-like strain (A/Wisconsin/67/2005 NYMCX-161B) 7.5 µg haemagglutinin and B/Malaysia/2506/2004 - like strain 7.5 µg haemagglutinin, in an aqueous suspension. An aqueous suspension is a buffered saline solution composed of: 2 mg sodium chloride, 50 µg potassium chloride, 287.5 µg sodium phosphate – dibasic dihydrate, 50 µg potassium phosphate – monobasic and water for injection to 0.25 mL.

The vaccine is prepared from virus grown in the allantoic cavity of embryonated eggs, inactivated by formaldehyde, purified by zonal centrifugation, and disrupted by a Triton X-100 process. This vaccine may contain < 10 picograms of neomycin.

The type and amount of viral antigens contained in VAXIGRIP[®] JUNIOR conform to the current requirements of the Influenza Vaccine Committee of the Commonwealth Department of Health and New Zealand Communicable Diseases Control Advisory Committee.

ACTIONS

Influenza vaccines have been shown to give antibody responses and to provide protection against clinical illness in a proportion of vaccinees. Because the influenza virus is capricious antigenically and because significant changes in its antigenic behaviour may occur from time to time, protection afforded by VAXIGRIP[®] JUNIOR is limited to the strains from which the vaccine has been prepared or to closely related strains.

VAXIGRIP[®] JUNIOR conforms in safety and sterility to the requirements of the British Pharmacopoeia.

INDICATIONS

VAXIGRIP[®] JUNIOR is indicated for the prevention of influenza caused by Influenza Virus types A and B especially in children from 6 months to 6 years who run an increased risk of associated complications. The current Australian National Health and Medical Research Council recommendations (The Australian Immunisation Handbook, 8th Edition, 2003) relevant to this age group are:

1. Individuals who are at increased risk of influenza-related complications

Annual vaccination is recommended for these groups:

- Children (6 months to 6 years old) with chronic disorders of the pulmonary or circulatory systems. This includes children with congenital heart disease and cystic fibrosis, and severe asthmatics such as those requiring frequent hospitalisations.
- Children (6 months to 6 years) with other chronic illness requiring regular medical follow-up or hospitalisation in the preceding year. This includes diabetes mellitus (and other chronic metabolic diseases), renal dysfunction, haemoglobinopathies, or immunosuppression (including immunosuppression caused by medication).
- Children (6 months to 6 years) on long-term aspirin therapy who therefore may be at risk of developing Reye's syndrome after influenza.

2. Those who can transmit influenza to persons at increased risk

Annual vaccination is recommended for, children 6 months to 6 years who are household members of persons in increased-risk groups.

3. Use of influenza vaccine in other groups

Influenza vaccine is recommended for:

- Children 6 months to 6 years infected with HIV.
- Child travellers 6 months to 6 years including those in one of the above risk groups and those who wish to reduce their chance of becoming infected with influenza. In particular, those child travellers in large tourist groups or travelling to the Northern Hemisphere from October to March, should consider influenza vaccination prior to departure, noting that, children who are vaccinated with the previous season's vaccine before travel should be revaccinated in the autumn with the current vaccine.

CONTRAINDICATIONS

Influenza virus is propagated in eggs for the preparation of influenza virus vaccine. Therefore, VAXIGRIP® JUNIOR should not be given to children with a history of hypersensitivity (allergy), especially anaphylactic reactions, to eggs or egg products. VAXIGRIP® JUNIOR should not be given to children known to have hypersensitivity to any components of the vaccine. Immunisation should not be performed during an acute feverish illness.

PRECAUTIONS

The contents of the syringe must be shaken thoroughly immediately before use. The syringes are for single use only and must not be used in more than one individual.

Do not administer by intravascular route. Ensure that the needle does not penetrate a blood vessel.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Since this vaccine contains traces of formaldehyde, octoxynol-9 (Triton X-100) and neomycin due to the use of these substances during production, it should be used with caution in subjects with a hypersensitivity to any of these substances.

Caution should be exercised when a patient with a history of an allergic condition such as asthma or dermatitis is to be given influenza vaccine.

Patients with a history of Guillain-Barré Syndrome (GBS) with an onset related in time to influenza vaccination may be at increased risk of again developing GBS if given influenza vaccine. While this risk should be weighed against the benefits to the individual patient of influenza vaccination, it would seem prudent to avoid subsequent influenza vaccination in this group.

Because patients with a history of GBS have an increased likelihood of again developing the syndrome, the chance of them coincidentally developing the syndrome following influenza vaccination may be higher than in individuals with no history of GBS.

As with other injectable vaccines, appropriate medical treatment and supervision should always be available in case of anaphylactic reactions. Adrenaline should always be ready for immediate use whenever any injection is given.

Use in Pregnancy (Category B2)

Not applicable. This vaccine is for use in children aged 6 months to 6 years.

Interactions

Influenza vaccine can impair the metabolism of warfarin, theophylline, phenytoin, phenobarbitone and carbamazepine by the hepatic P450 system. Results from studies have been variable in degree of interaction and time after vaccination for the interaction to take effect. The interaction may be idiosyncratic. Patients taking warfarin, theophylline, phenytoin, phenobarbitone or carbamazepine should be advised of the possibility of an interaction and told to look out for signs of elevated levels of medication.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique can be used to disprove these results. The transient false positive reactions could be due to IgM response by the vaccine.

ADVERSE REACTIONS

Children usually react more strongly to influenza vaccines than adults. However, split virion (split virus) influenza vaccines have been found to be less reactive than whole virus vaccines.

The following reactions are most common:

- Local reactions, consisting of swelling, redness, ecchymosis, induration, pruritus, tenderness and/or pain.
- Systemic reactions, consisting of fever of short duration, malaise, shivering, tiredness, headache, sweating, myalgia, arthralgia, and lymphadenopathy.

These reactions usually disappear within 1-2 days without treatment.

Allergic reactions: urticaria, pruritus, erythematous rash, dyspnoea, and angioedema, exceptionally leading to shock have been reported.

The following events are observed rarely: neuralgia, paraesthesia, convulsion, and transient thrombocytopenia.

Neurological disorders, such as encephalomyelitis, neuritis, and Guillain Barré Syndrome have been reported.

Post vaccination neurological disorders have been reported following the use of almost all biological products. Guillain-Barré Syndrome (GBS) has been very rarely reported in temporal association with administration of influenza vaccines. In the 1976 swine influenza vaccination program the U.S. Public Health Advisory Committee on Immunisation Procedures (ACIP) found that GBS occurred at an incidence of approximately 1 in 100,000 after immunisation and that the death rate in this 'series' was approximately 1 in 2,000,000. Such an excess incidence of GBS has not been demonstrated in subsequent years when recipients of the 1978 and 1979 vaccines were studied. An association between Guillain-Barré Syndrome and the Influenza vaccines used in the Northern Hemisphere USA in the 1992-93 and 1993-94 seasons has been reported. The excess cases of Guillain-Barré Syndrome attributed to Influenza vaccination was 1 to 2 cases for each million persons vaccinated.

Very rarely cases of vasculitis with transient renal involvement, arthritis, LE rash and LE syndrome or polymyalgia rheumatica have been reported following vaccination with inactivated influenza vaccine, however the causality has not been established.

Although allergic reactions are not seen commonly with VAXIGRIP[®] Junior, they may occur rarely. Adrenaline should be readily available to treat such reactions.

DOSAGE AND ADMINISTRATION

Immunisation is normally undertaken in the autumn, in anticipation of winter outbreaks of influenza.

One dose is usually sufficient for those persons previously exposed to viruses of similar antigenic content to the strains present in the vaccine. In children lacking such experience and in those with some impairment of immune mechanisms, two doses separated by an interval of at least one month are recommended.

The vaccine should be administered by intramuscular or deep subcutaneous injection.

Infants and Children 6 months to 35 months: 0.25 mL.

Note: VAXIGRIP® JUNIOR should be administered to children under 5 years of age with care (see INDICATIONS; ADVERSE REACTIONS).

The Australian National Health and Medical Research Council recommends that influenza vaccine can be administered concurrently with other vaccines, including pneumococcal polysaccharide vaccine and all the scheduled childhood vaccines (see Australian Immunisation Handbook, 8th edition, 2003 page 171).

PRESENTATION

Syringe containing 0.25 mL of vaccine.
Packs of 1 or 10 syringes

STORAGE

Store at 2°C to 8°C. Do not freeze. Protect from light.

MANUFACTURER

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POISON SCHEDULE
S4 PRESCRIPTION ONLY MEDICINE

TGA APPROVAL DATE
30 August 2006 – Dosage amendment

Date of most recent amendment
October 2006 – Formulation change
December 2006 – Safety related change

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