

# VAXIGRIP® JUNIOR

## Inactivated Influenza Vaccine (Split Virion)

---

### Description

---

VAXIGRIP® JUNIOR is a sterile suspension of influenza virus for intramuscular or deep subcutaneous injection. It is a purified, inactivated, split virion vaccine.

VAXIGRIP® JUNIOR contains the following strains of influenza virus:

- A/California/7/2009 NYMC X-179A (A/California/7/2009 [H1N1] - like),
- A/Victoria/210/2009 NYMC X-187 (A/Perth/16/2009 [H3N2] – like)
- B/Brisbane/60/2008 (B/Brisbane/60/2008 - like)

Each 0.25mL pre-filled syringe contains 7.5 mcg haemagglutinin of each of the 3 strains in a buffered saline solution. A buffered saline solution contains the following excipients – sodium chloride, potassium chloride, sodium phosphate – dibasic dehydrate, potassium phosphate – monobasic and water for injection.

The vaccine is prepared from virus grown in the allantoic cavity of embryonated eggs, concentrated, purified by zonal centrifugation in a sucrose gradient, split by octoxinol 9 (Triton X-100), inactivated by formaldehyde and then diluted in phosphate buffered saline solution to the required concentration. The vaccine may contain traces of formaldehyde ( $\leq 15$  mcg), octoxinol 9 ( $\leq 100$  mcg) and neomycin ( $< 10$  picogram). VAXIGRIP® JUNIOR does not contain more than 0.025 mcg ovalbumin per dose.

The type and amount of viral antigens contained in VAXIGRIP® JUNIOR conform to the annual requirements of the Australian Influenza Vaccine Committee (AIVC) and the World Health Organisation (WHO) recommendations for the season. VAXIGRIP® JUNIOR conforms in safety and sterility to the requirements of the British Pharmacopoeia.

---

### Pharmacology

---

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.

Seroprotection is generally obtained within 2 to 3 weeks. The duration of post vaccinal immunity varies and is usually 6 to 12 months.

---

### Indications

---

VAXIGRIP® JUNIOR is indicated for the prevention of influenza caused by Influenza Virus types A and B in children from 6 months to 35 months who run an increased risk of associated complications.

The current New Zealand Immunisation Handbook recommends annual vaccination for the following children:

Children with:

- Cardiovascular disease – ischaemic heart disease, congestive heart failure, rheumatic heart disease, congenital heart disease, cerebrovascular disease.
- Chronic respiratory disease – Asthma if on regular preventative therapy; other chronic respiratory disease with impaired lung function.
- Diabetes.
- Chronic renal disease.
- Any cancer, excluding basal or squamous skin cancers if not invasive.
- Other conditions – autoimmune disease, immune suppression, HIV, transplant recipients, neuromuscular and CNS diseases, haemoglobinopathies, children on long-term aspirin.

Other children

Healthy children in close contact with individuals at high risk of complications.

For full details regarding these recommendations for influenza vaccination, refer to the current New Zealand Immunisation Handbook.

---

## Contraindications

---

VAXIGRIP® JUNIOR should not be given to children known anaphylactic hypersensitivity reactions to egg proteins (egg or egg products), chicken proteins, or any other component of the vaccine including traces (formaldehyde, octoxinol 9 (Triton X-100) and neomycin).

Immunisation should not be performed during an acute febrile illness.

---

## Precautions

---

Since this vaccine contains traces of formaldehyde, octoxinol-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.

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.

The immune response to this vaccine may be insufficient in persons deficient in producing antibodies, whether due to genetic defect, immunodeficiency disease, or immunosuppressive therapy.

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

As with all injectable vaccines, the vaccine must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

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 35 months.

## **Use in Lactation**

Not applicable. This vaccine is for use in children aged 6 months to 35 months.

## **Interactions**

Influenza vaccine can impair 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 including febrile convulsions, 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.

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

**Table 1: Dosage recommendations**

| Age                   | Dose    | No. of doses        | No. of doses <sup>(1)</sup> |
|-----------------------|---------|---------------------|-----------------------------|
|                       |         | (first vaccination) | (subsequent years)          |
| 6 months to 35 months | 0.25 mL | 2                   | 1                           |

(1) Where children 6 months to 35 months of age receiving influenza vaccine for the first time have not received the second dose within the same year, they should be given 2 doses the following year.

\* For children aged  $\leq$  35 months who are receiving influenza vaccine for the first time, it is recommended that they receive 2 doses at least 1 month apart.

Note: VAXIGRIP® JUNIOR should be administered to children under 35 months of age with care (see INDICATIONS; ADVERSE REACTIONS).

The contents of the syringe must be shaken thoroughly immediately before use. After shaking, the vaccine is a slightly whitish and opalescent liquid.

Syringes are for single use only and must not be used in more than one individual.

The current New Zealand Immunisation Handbook recommends that influenza vaccine can be administered concurrently with all the scheduled childhood vaccines. When administering VAXIGRIP® JUNIOR concurrently with other vaccines, separate syringes and different injection sites should be used.

---

### Overdosage

---

No specific information exists on overdosage with VAXIGRIP® JUNIOR.

For general advice on overdose management, contact the New Zealand National Poisons Centre on 0800 764 766.

---

### Presentation

---

Pre-filled 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**

---

Sanofi Pasteur S.A.

Lyon, France

---

**Distributor**

---

New Zealand:

sanofi-aventis new zealand limited

Level 8, James and Wells Tower

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 727 838

---

**Medicines Classification**

---

PRESCRIPTION ONLY MEDICINE

---

**Date of Preparation**

---

20 December 2010

---

® VAXIGRIP is a registered trademark of Sanofi Pasteur SA