

Fluvax[®]

**WARNING: This season's vaccine is indicated for use only in persons aged 5 years and over.
See Indications and Precautions.**

For season 2012

Name of the Medicine

Fluvax[®] vaccine
Inactivated influenza vaccine (split virion)

Description

This is a purified, inactivated, split virion (split virus) vaccine each 0.5 mL of which contains antigens representative of the following types:

A/California/7/2009 (NYMC X-181) (A/California/7/2009 (H ₁ N ₁) – like):	15 µg haemagglutinin per dose
A/Victoria/210/2009 (NYMC X-187) (A/Perth/16/2009 (H ₃ N ₂) – like):	15 µg haemagglutinin per dose
B/Brisbane/60/2008 (B/Brisbane/60/2008 – like):	15 µg haemagglutinin per dose

Each 0.5 mL dose also contains, nominally: sodium chloride 4.1 mg, sodium phosphate - dibasic anhydrous 0.3 mg, sodium phosphate – monobasic 0.08 mg, potassium chloride 0.02 mg, potassium phosphate – monobasic 0.02 mg and calcium chloride 1.5 µg.

The following are present in each 0.5 mL dose: sodium taurodeoxycholate ≤ 5 µg, ovalbumin ≤ 1 µg, sucrose < 10 µg, neomycin ≤ 3 ng, polymyxin B sulfate ≤ 0.5 ng and β-propiolactone ≤ 0.4 ng.

The type and amount of viral antigens in Fluvax[®] vaccine conform to the requirements of the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health for the winter of 2012. The strains chosen for vaccine manufacture are endorsed by the Australian Influenza Vaccine Committee as being antigenically equivalent to the reference virus.

The vaccine is prepared from virus grown in the allantoic cavity of embryonated eggs, purified by zonal centrifugation, inactivated by β-propiolactone and disrupted by sodium taurodeoxycholate. Fluvax[®] vaccine conforms in safety and sterility to the requirements of the British Pharmacopoeia.

Pharmacology

Fluvax[®] vaccine has been shown to induce antibodies to the viral surface glycoproteins, haemagglutinin and neuraminidase. These antibodies are important in the prevention of natural infection.

Seroprotection is generally obtained within 2 to 3 weeks. The duration of post vaccination immunity to homologous strains or to strains closely related to the vaccine strains varies, but is usually 6 to 12 months.

Indications

For the prevention of influenza caused by Influenza Virus, Types A and B. For the Southern Hemisphere 2012 season, the vaccine is indicated for use only in persons aged 5 years and over.

See Precautions and Dosage and Administration.

For full details regarding recommendations for influenza vaccination, please refer to the relevant national immunisation guidelines.

Contraindications

Anaphylactic hypersensitivity to previous influenza vaccination or to eggs, neomycin, polymyxin B sulfate or any of the constituents or trace residues (see Description section) of this vaccine.

Immunisation must be postponed in people who have febrile illness or acute infection.

Precautions

During the 2010 Southern Hemisphere influenza season, there was an unexpected increase in reports of fever and febrile convulsions in children aged less than 5 years following seasonal influenza vaccination. Febrile convulsions were reported uncommonly (i.e. reporting frequency estimated to be in the range $\geq 1/1000$ to $< 1/100$)*. The vaccine is only indicated for use for Southern Hemisphere season 2012 in persons aged 5 years and over.

(*estimated from epidemiological investigations)

See Indications and Dosage and Administration.

Febrile events were also observed in children 5 to under 9 years. Therefore in this age group a decision to vaccinate with the 2012 Southern Hemisphere formulation of Fluvax[®] vaccine should be based on careful consideration of potential benefits and risks in the individual.

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.

Minor illness with or without fever should not contraindicate the use of influenza vaccine.

In immunocompromised patients, the antibody response may be lower.

If Guillain-Barré syndrome has occurred within 6 weeks of previous influenza vaccination, the decision to give Fluvax[®] vaccine/Fluvax[®] Junior vaccine should be based on careful consideration of the potential benefits and risks.

Use in Pregnancy: Category B2

It is recommended that influenza immunisation be offered in advance to women planning a pregnancy, and to pregnant women who will be in the second or third trimester during the influenza season, including those in the first trimester at the time of vaccination.

An animal reproduction study has been conducted with CSL Influenza Vaccine. This study did not demonstrate any maternal or developmental toxicity.

Use in Lactation:

The vaccine has not been evaluated in nursing mothers.

Interactions with other medicines:

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

Fluvax[®] vaccine can be administered concurrently with other vaccines, however separate syringes and separate injection sites should be used.

Adverse Effects

Clinical trials:

Paediatric study (CSLCT-FLU-04-05)

The safety, tolerability and immunogenicity of Fluvax[®] vaccine in a paediatric population (≥ 6 months to < 3 years and ≥ 3 years to < 9 years) were demonstrated in an open label, multi-centre study (CSLCT-FLU-04-05). Participants who had not been previously vaccinated against influenza were stratified and vaccinated according to age: Group A: ≥ 6 months to < 3 years received two 0.25 mL doses and Group B: ≥ 3 years to < 9 years received two 0.5 mL doses. The total number of participants was 298 (Group A n=151; Group B n=147). The study also included a 12 month follow up dose. The total number of participants for the 12 month follow up dose was 273 (Group A n = 76; Group B n = 197). Although the H1N1 strain was the same, both H3N2 and B strains in the vaccine formulation were different in the 12 month follow up dose.

There were no reports of serious adverse events (SAEs) related to Fluvax[®] vaccine during the primary vaccination period. Two SAEs assessed as causally related to the vaccine were reported after the 12 month follow up dose. One Group B participant experienced vomiting and fever that necessitated hospitalisation for rehydration. Another Group B participant experienced vomiting and febrile convulsion and was observed in a hospital emergency department for 2 hours.

Table 1 presents the proportion of participants with solicited adverse events within 7 days after administration of Fluvax[®] vaccine. The table includes all adverse experiences reported with an incidence of 2% or greater. A dash represents an incidence of less than 2%. Unsolicited adverse events were collected for 30 days post-vaccination. Very common unsolicited events ($\geq 1/10$) reported were rhinitis, cough, teething and influenza-like illness. Following the 12 month follow up dose, the very common unsolicited events ($\geq 1/10$) reported by Group A were cough and rhinorrhoea.

Table 1: Proportion of Paediatric Subjects with Solicited Local and Systemic Adverse Events within 7 days of Administration of Fluvax[®] vaccine

Solicited Adverse Event	Group A (≥ 6 months to < 3 years) %			Group B (≥ 3 years to < 9 years) %		
	Dose 1 (n = 151)	Dose 2 (n = 151)	12 month follow up dose (n = 76)	Dose 1 (n = 147)	Dose 2 (n = 147)	12 month follow up dose (n = 196 [#])
Local						
Pain	36.4	37.1	51.3	59.2	61.9	71.4
Erythema	35.8	37.7	43.4	36.7	45.6	43.4
Swelling	15.9	20.5	25.0	24.5	27.2	26.0
Systemic						
Irritability	47.7	41.1	38.2	20.4	17.0	32.1
Rhinitis	37.1	47.7	35.5	21.1	28.6	29.6
Fever*	22.5	22.5	39.5	15.6	8.2	27.0
Cough	21.2	31.8	22.4	19.0	19.0	16.8
Loss of appetite	19.2	23.8	21.1	7.5	5.4	16.8
Vomiting/ Diarrhoea	14.6	13.9	17.1	7.5	6.8	13.8
Headache	2.0	3.3	-	13.6	10.9	25.0
Myalgia	-	2.7	6.6	13.6	8.2	11.7
Earache	3.3	3.4	-	4.1	-	-
Sore throat	2.0	5.3	6.6	8.2	10.9	10.2
Wheezing/ Shortness of breath	3.3	8.6	3.9	2.7	2.0	4.6

* Axillary Temperature ≥ 37.5°C or Oral Temperature ≥ 38.0°C

[#] One Group B participant was given the 0.25 mL dose and was excluded from subsequent, per protocol safety analyses. Accordingly, there were 196 participants included in Group B.

Adult studies (CSLCT-NHF-04-99, CSLCT-NHF-05-11 and CSLCT-NHF-05-13)

The safety, tolerability and immunogenicity of CSL Influenza Vaccine in adult (≥ 18 to < 60 years) and older adult (≥ 60 years) populations were demonstrated in 3 clinical studies (CSLCT-NHF-04-99, CSLCT-NHF-05-11 and CSLCT-NHF-05-13). Total number of participants were similar for each age group (adults n=222 and older adults n=224). There were no reports of serious adverse events related to CSL Influenza Vaccine during the vaccination period. Table 2 presents the proportion of participants with solicited adverse events within 4 days of administration of CSL Influenza Vaccine. The table includes all adverse experiences reported with an incidence of 2% or greater. A dash represents an incidence of less than 2%. Unsolicited adverse events of more than 2 days duration were collected up to day 21 after vaccination. The most common unsolicited event reported was upper respiratory tract infection which occurred in 1.3% of participants (adult and older adults).

Table 2: Proportion of Adult and Older Adult Subjects with Solicited Local and Systemic Adverse Events within 4 days of Administration of CSL Influenza Vaccine

Solicited Adverse Event	Adult (n = 222) (≥ 18 to < 60 years) %	Older Adult (n = 224) (≥ 60 years) %
Local		
Pain	36.0	12.9
Erythema	18.5	11.2
Ecchymosis	6.8	5.4
Systemic		
Malaise	13.1	-
Chills / Shivering	2.3	-

Post-marketing surveillance:

The following adverse events have been spontaneously reported during post-approval use of Fluvax[®] vaccine and are in addition to the events observed during clinical trials. The adverse events reported are presented below according to System Organ Class.

Blood and Lymphatic System Disorders

Transient thrombocytopenia.

Immune System Disorders

Allergic reactions including anaphylactic shock.

Nervous System Disorders

Neuralgia, paraesthesia and convulsions (including febrile convulsions).
Encephalitis, neuritis or neuropathy and Guillain-Barré syndrome.

Vascular Disorders

Vasculitis with transient renal involvement.

Skin and Subcutaneous Tissue Disorders

Pruritus, urticaria and rash.

Dosage and Administration

Immunisation should be undertaken in anticipation of seasonal outbreaks of influenza.

To provide continuing protection, annual vaccination with vaccine containing the most recent strains is necessary.

Dosage:

See Indications and Precautions.

Adults and children from 5 years: 0.5 mL

One dose is sufficient for persons previously exposed to viruses of similar antigenic composition to the strain(s) present in the vaccine. For children under 9 years who have not previously been vaccinated, a second dose should be given after an interval of at least four weeks.

Administration:

It is important that the contents of the container be shaken thoroughly immediately before use.

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

Fluvax[®] vaccine is presented as a single-use syringe and any remaining contents should be discarded.

Overdosage

There is no specific information on overdose of CSL Influenza Vaccine.

For general advice on overdose management:

In Australia, contact the Poisons Information Centre on 131 126.

In New Zealand, call the New Zealand Poisons Centre on 0800 POISON or 0800 764 766.

Presentation and Storage Conditions

Presentation:

Each disposable syringe contains a single 0.5 mL dose of vaccine.

The Fluvax[®] vaccine syringe is supplied encased within a clear film wrapper. The presence of the film wrapper provides assurance that the product has not been opened. Do not use if the film wrap is damaged or missing.

Storage Conditions:

Fluvax[®] vaccine should be stored, protected from light, at 2°C to 8°C. IT MUST NOT BE FROZEN.

Medicine Classification

Prescription Medicine.

Name and Address

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