Fluvax®

INACTIVATED INFLUENZA VACCINE (SPLIT VIRION)

For the prevention of influenza caused by Influenza Virus, Types A and B

Season 2010

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_1N_1) – like)	15 µg haemagglutinin per dose
A/Wisconsin/15/2009 (NYMC X-183) (A/Perth/16/2009 (H_3N_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 ≤ 0.7 ng, polymyxin B sulfate ≤ 0.11 ng and β-propiolactone ≤ 1.4 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 2010. 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 full details regarding recommendations for influenza vaccination, please refer to the relevant national immunisation guidelines.

CONTRAINDICATIONS

Hypersensitivity to eggs, chicken protein or any of the constituents or trace residues of this vaccine.

Immunisation must be postponed in people who have febrile illness or acute infection. However, minor illness with or without fever should not contraindicate the use of influenza vaccine.

PRECAUTIONS

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.

In immunocompromised patients, the antibody response may be lower.

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.

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). There were no reports of serious adverse events related to Fluvax® vaccine during the vaccination period. 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 (≥ 1/10) reported were rhinitis, cough, teething and influenza-like illness.

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 (n = 151) (≥ 6 months to < 3 years) %		Group B (n = 147) (≥ 3 years to < 9 years) %	
	Dose 1	Dose 2	Dose 1	Dose 2
Local				
Pain	36.4	37.1	59.2	61.9
Erythema	35.8	37.7	36.7	45.6
Swelling	15.9	20.5	24.5	27.2
Systemic				
Irritability	47.7	41.1	20.4	17.0
Rhinitis	37.1	47.7	21.1	28.6
Fever*	22.5	22.5	15.6	8.2
Cough	21.2	31.8	19.0	19.0
Loss of appetite	19.2	23.8	7.5	5.4
Vomiting/ Diarrhoea	14.6	13.9	7.5	6.8
Headache	2.0	3.3	13.6	10.9
Myalgia	-	2.7	13.6	8.2
Earache	3.3	3.4	4.1	-
Sore throat	2.0	5.3	8.2	10.9
Wheezing/ Shortness of breath	3.3	8.6	2.7	2.0

* Axillary Temperature ≥ 37.5ºC or Oral Temperature ≥ 38.0ºC

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

The safety, tolerability and immunogenicity of Fluvax® 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). Table 2 presents the proportion of participants with solicited adverse events within 4 days of 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 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 Fluvax® 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 experiences have been spontaneously reported during post-approval use of Fluvax® vaccine. The adverse events reported are presented below according to System Organ Class and frequency.

Adverse event frequencies are defined as follows: Very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1,000, < 1/100), rare (≥ 1/10,000, < 1/1,000) and very rare (< 1/10,000).

Blood and Lymphatic System Disorders

Rare: Transient thrombocytopenia.

Immune System Disorders

Rare: Allergic reactions including anaphylactic shock.

Nervous System Disorders

Rare: Neuralgia, paraesthesia and convulsions.

Very rare: Encephalitis, neuritis or neuropathy and Guillain-Barré syndrome.

Vascular Disorders

Very rare: Vasculitis with transient renal involvement.

Skin and Subcutaneous Tissue Disorders

Uncommon: Pruritus, urticaria and rash.

General Disorders and Administration Site Conditions

Very Common: Injection site inflammation.

Common: Influenza-like illness.

Injection site ecchymosis and induration.

Influenza-like illness may include pyrexia, chills, headache, malaise and myalgia.

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

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:

Children 6 months to 35 months: 0.25 mL

Adults and children from 36 months: 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.

Before administering the 0.25 mL paediatric dose, carefully discard half the volume from the syringe, which is prefilled with 0.5 mL. To do so, depress the plunger to the half dose marking on the glass syringe barrel. Inject the remaining 0.25 mL of vaccine.

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, 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 2ºC to 8ºC. IT MUST NOT BE FROZEN.

MEDICINE CLASSIFICATION

Prescription Medicine.

NAME AND ADDRESS

Manufactured by:

CSL Limited ABN 99 051 588 348
45 Poplar Road Parkville
VICTORIA 3052 AUSTRALIA

Distributed by:

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