

Fluvax[®]

Inactivated Influenza Vaccine (Split Virion)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Fluvax[®]** vaccine.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor considers the risks of you or your child having **Fluvax[®]** vaccine and the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Fluvax[®] vaccine is used for

Fluvax[®] vaccine helps prevent influenza, often called "the flu". Influenza is caused by infection with specific influenza viruses. New types of influenza virus can appear each year. **Fluvax[®]** vaccine contains fragments of three different types of influenza virus. Each year the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health decide which three types of virus are most suitable.

The virus in the vaccine is killed. Therefore the vaccine will not give you or your child "the flu".

Note: the vaccine will not protect you or your child from the other influenza viruses that **Fluvax[®]** vaccine does not contain.

Fluvax[®] vaccine is available only with a doctor's prescription. This year (2004) the viruses are A/New Caledonia, A/Fujian and B/Hong Kong.

Vaccination against influenza is recommended every year, for anyone wanting to lower their chance of catching influenza. Influenza vaccination is particularly recommended for the following groups of people who are considered at high risk from influenza:

- those 65 years of age or older
- Aboriginal and Torres Strait Islanders 50 years of age or older
- Aboriginal and Torres Strait Islanders 15 to 49 years of age with medical conditions
- those 6 months of age or older who have heart, lung or blood circulation diseases. This includes, for example, people with heart problems, people with cystic fibrosis and people who need to be admitted to hospital frequently because of asthma
- those 6 months of age or older who have other chronic illnesses such as: sugar diabetes, kidney problems, poor immunity (including people with HIV) or abnormal haemoglobin (for example sickle cell disease)
- people living in nursing homes, hostels or other long-term care facilities
- people who have contact with anyone from the groups of people listed above

Fluvax[®] vaccine is also likely to benefit:

- people with asthma, especially those with severe asthma

- children 6 months to 10 years on long-term aspirin therapy
- women who will be 4 to 9 months pregnant during the influenza season. They should be vaccinated in advance
- people in the workplace, especially if influenza is very common
- travellers

How Fluvax[®] vaccine works

Fluvax[®] vaccine works by causing your body to protect against infection by influenza viruses, types A and B that are in the vaccine.

The body makes substances, called antibodies. Antibodies fight the influenza virus. When you have been vaccinated and later come into contact with those influenza viruses in the vaccine, your body is usually ready to kill them. This prevents you from getting influenza.

Your body takes a few weeks after vaccination to fully develop protection against the influenza virus.

Protection against influenza requires one dose of **Fluvax[®]** vaccine. Sometimes, a follow up (booster) dose may also be given. Your doctor will tell you if you or your child need another dose.

Most people make satisfactory antibodies against the influenza virus. However, as with all vaccines, 100% protection cannot be guaranteed.

The chance of having a severe unwanted reaction after having **Fluvax[®]** vaccine is very small. The risks from not being vaccinated against influenza may be very serious.

Before you are given Fluvax[®] vaccine

When you or your child must not be given Fluvax[®] vaccine

Do not have Fluvax[®] vaccine if you or your child have or previously had an allergy to:

- Fluvax[®] vaccine or any of the ingredients listed at the end of this leaflet
- eggs and/or chicken feathers
- the antibiotics neomycin or polymyxin

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not have Fluvax[®] vaccine if you or your child have/has a temperature higher than 38.5°C.

Fluvax[®] vaccine is not recommended for use in children under 3 months.

Do not have Fluvax[®] vaccine after the expiry date printed on the pack.

Do not have Fluvax[®] vaccine if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have Fluvax[®] vaccine, talk to your doctor or pharmacist.

Before you or your child are given Fluvax[®] vaccine

Tell your doctor if in the past you or your child have/has reacted to vaccination with any of the following:

- severe allergic reaction
- difficulty breathing
- swelling of the throat
- fainting or collapse
- fits or convulsions
- high temperature (greater than 38.5°C)

- severe skin reaction at the injection site, including severe bruising

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay vaccination until your illness has passed. A minor illness such as a cold is not usually a reason to delay vaccination.

Tell your doctor if in the past you or your child have had any medical conditions, especially the following:

- low immunity due to ill-health, for example some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- low immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines, used to treat cancer (including radiation therapy)
- allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue
- Guillain-Barré Syndrome (GBS), an illness which affects the nervous system and causes paralysis

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having Fluvax[®] vaccine during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having Fluvax[®] vaccine while you are breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Fluvax[®] vaccine may interfere with each other.

The following medicines or treatments may affect how well Fluvax[®] vaccine works:

- medicines which affect the body's immune response, such as corticosteroids, cyclosporin or
- some treatments for cancer (including radiation therapy)

Also, after you have Fluvax[®] vaccine, your usual dose of some medicines may be affected. These medicines include:

- carbamazepine, used in epilepsy or convulsions
- phenobarbitone, used in epilepsy or convulsions, anxiety, insomnia
- phenytoin, used in epilepsy or convulsions
- theophylline, used for asthma
- warfarin, used to prevent blood clots

Your doctor will tell you what to look out for if this happens. For a time you may need a different dose of these medicines or you may need to take a different medicine.

Your doctor or pharmacist will help you decide whether or not you should have the vaccine.

Having other vaccines

Tell your doctor if you have had any vaccines in the last 4 weeks.

Your doctor will tell you if Fluvax[®] vaccine is to be given at the same visit as another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid when you are given Fluvax[®] vaccine.

How Fluvax[®] vaccine is given

Fluvax[®] vaccine is given by injection by a trained health professional. In adults it is usually injected into the upper arm. In babies, Fluvax[®] vaccine is usually given in the upper thigh.

Fluvax[®] vaccine should not be injected directly into a blood vessel.

Fluvax[®] vaccine should be given at facilities able to manage any allergic reaction. Allergy to Fluvax[®] vaccine is uncommon, but allergy to any vaccine may occur.

How much is given

Fluvax[®] vaccine injection is given once every year, as follows:

- Children over 6 years and adults: one injection of 0.5 mL
- Children 2 to 6 years: one injection of 0.25 mL
- Children 3 months to 2 years: one injection of 0.125 mL

Your doctor may recommend a second (booster) injection of Fluvax[®] vaccine 4 weeks after the first injection. This is likely to be recommended for children or adults with low immunity.

Overdose is unlikely as your health professional gives you the injection and it is pre-packed in individual single-use syringes.

If you have any concerns, ask your doctor or pharmacist.

When it is given

Fluvax[®] vaccine is usually given in autumn, before the outbreaks of influenza which generally occur in winter.

If you miss a dose

Your doctor may advise that you or your child should have a second injection of Fluvax[®] vaccine 4 weeks after the first dose. If you miss the follow-up dose, talk to your doctor and arrange another visit as soon as possible.

After having Fluvax[®] vaccine

Things you or your child must do

Keep an updated record of your vaccinations.

Keep any follow-up appointments with your doctor or clinic.

It is important to have your follow-up dose of Fluvax[®] vaccine at the appropriate time. This ensures the vaccine has the best chance of providing protection against 'the flu'.

Have blood tests if your doctor advises.

Your doctor may wish to check that you have developed protection (antibodies) against influenza.

If you develop any medical problems after being given Fluvax[®] vaccine, tell your doctor.

Fluvax[®] vaccine is very unlikely to affect your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child feel unwell after having Fluvax[®] vaccine.

Fluvax[®] vaccine may have unwanted side effects in some people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment for some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- reaction around the injection site such as redness, burning, itchiness, tenderness, pain or

discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars

- flushing, redness or skin rash, especially affecting the face
- generally feeling unwell
- flu-like symptoms, such as headache, fatigue, high temperature (fever), sore throat, runny nose, cough, chills, sweating, nausea, vomiting, and dizziness
- soreness, aching muscles or joints, muscle tenderness or weakness

These are the more common side effects of Fluvax[®] vaccine. Mostly these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- infection at the injection site
- unusual bleeding, bruising or purple spots anywhere on the skin
- skin rash, itchy spots or red lumps on the skin
- painful, swollen joints
- tingling, numbness or weakness

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- An allergic reaction: Typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing
- a fit, convulsion or seizure
- muscles: feel sore or tender, extremely weak, lose strength or movement
- Urine: there is little or no urine
- skin bruising, which is painful or swollen
- pain, swelling and heat in joints, skin, muscle or other parts of the body
- headache and high temperature with for example hallucinations, confusion, paralysis of part or all

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of the body, behaviour, disturbance, speech and eye movements, sensitivity to light. Very rarely, a serious disorder called Guillain-Barré syndrome occurs. This affects the nervous system and causes paralysis.

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Other side effects not listed may occur in some patients. Tell your trained health professional if you notice anything that makes you or your child feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Storing Fluvax[®] vaccine

Fluvax[®] vaccine is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store Fluvax[®] vaccine:

- **Keep it where children cannot reach it**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Fluvax[®] vaccine. Protect it from light.**
Note: Freezing destroys the vaccine.
- **Keep Fluvax[®] vaccine in the original pack until it is time for it to be given**

Fluvax[®] vaccine should not be used after the expiry date on the label.

Product description

What it looks like

Fluvax[®] vaccine is in a pre-filled disposable syringe (with attached needle) for one usage only. Your trained health professional will give you the injection.

Ingredients

Active ingredients:

- Purified, inactivated virus fragments from influenza types:
 - H₁N₁ strain 15 micrograms
 - H₃N₂ strain 15 micrograms
 - B strain 15 micrograms

for the Southern Hemisphere winter season.

Other ingredients

- Sodium chloride
- Sodium phosphate - monobasic
- Sodium phosphate - dibasic anhydrous
- Potassium chloride
- Potassium phosphate - monobasic

Fluvax[®] vaccine may also contain traces of egg proteins, neomycin, polymyxin, sucrose and detergent (sodium taurodeoxycholate)

Fluvax[®] vaccine does not contain lactose, gluten, tartrazine or any azo dyes.

Ask your doctor or pharmacist if you are unsure about anything or want more information about Fluvax[®] vaccine.

Manufacturer/Distributor/Supplier

Fluvax[®] vaccine is made in Australia by:

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

Distributor

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