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, nurse 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 viruses 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 viruses are most suitable to include in the vaccine.

The virus in the vaccine has been killed. Therefore the vaccine cannot 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 (2018) the viruses are A/Michigan/45/2015 (H1N1) pdm09 – like virus, A/Singapore /INFIMH-16-0019/2016 (H3N2) - like virus and B/Phuket/3073/2013 – like virus.

Vaccination against influenza is recommended every year, for anyone wanting to lower their chance of catching influenza.

How Fluvax® vaccine works

Fluvax® vaccine works by causing your body to protect itself against infection by the influenza viruses, types A and B, that are in the vaccine. The vaccine stimulates the body to make substances, called antibodies. Antibodies fight the influenza virus. If you have been vaccinated, when you come into contact with the influenza viruses in the vaccine, your body is usually able quickly to destroy the virus. 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 generally 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 a follow up 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. Whereas, the risks of 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

Your child must not be given Fluvax® vaccine if they are under 5 years old. For the 2018 influenza season, Fluvax® vaccine is only for use in children aged 5 years and over.

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

- **Fluvax®** vaccine or any of the ingredients listed at the end of this leaflet
- Eggs
- the antibiotics neomycin or polymyxin B sulfate.

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 38.5ºC.

Do not have Fluvax® vaccine after the expiry date printed on the packaging.

The Fluvax® vaccine syringe is supplied encased in a blister pack inside a cardboard carton. The presence of the blister pack provides assurance that the product has not been opened. Do not use the vaccine if the blister pack (seal or backing) is damaged or missing.

If you are not sure whether you or your child should have Fluvax® vaccine, talk to your doctor, nurse 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 or your child have an infection or temperature higher than 38.5°C.

Your doctor may decide to delay vaccination until the 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 or your child have allergies to:

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

Tell your doctor if you are pregnant, or are planning to become pregnant.
Your doctor will discuss the potential risks and benefits of having **Fluvax®** vaccine during pregnancy, and advise on the timing of **Fluvax®** vaccination with regards to pregnancy.

Tell your doctor if you are breast-feeding.
Your doctor will discuss the potential risks and benefits of having **Fluvax®** vaccine while you are breast-feeding.

Taking other medicines

Tell your doctor, nurse or pharmacist if you or your child 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).

Your doctor, nurse or pharmacist will help you decide whether or not you or your child should have the vaccine.

Having other vaccines

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

Fluvax® vaccine can be given at the same time as other vaccines.

Your doctor will tell you if **Fluvax®** vaccine is to be given at the same time as another vaccine.

How Fluvax® vaccine is given

How it is given

Fluvax® vaccine is given by a doctor or nurse, as an injection into a muscle or under the skin.

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 is given once every year, as follows:

- Adults and children 5 years and over: one injection of 0.5 mL

For children 5 to under 9 years old who are receiving influenza vaccine for the first time it is recommended that a follow-up (booster) dose of **Fluvax®** vaccine is given 4 weeks after the first dose.

If the follow-up dose is missed, talk to your doctor and arrange another visit as soon as possible.

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

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

When it is given

Fluvax® vaccine is usually given before the start of the influenza season.

Vaccination should be repeated every year as new types of influenza virus can appear each year.

After having Fluvax® vaccine

Things you or your child must do

Keep an updated record of you and your child's vaccinations.

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

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child feel unwell after having the vaccine.

Fluvax® vaccine may have unwanted side effects in a few 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.

During the 2010 Southern Hemisphere influenza season, there was an unexpected increase in reports of fever and febrile convulsions (a fit or seizure caused by a fever) in children under 5 years of age. Side effects associated with fever were also seen in children 5 to under 9 years. Your doctor will assess and advise if it is appropriate for your child to receive the 2018 **Fluvax®** vaccine, depending on your child's underlying medical condition.

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

The following are the more common side effects of **Fluvax®** vaccine. Mostly these are mild and short-lived.

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

- reaction around the injection site such as tenderness, bruising, redness, warmth, pain, swelling or the formation of hard lumps
- flu-like symptoms, such as headache, tiredness, fever, sore throat, runny nose, blocked nose, sneezing, cough, chills
- vomiting, nausea, diarrhoea
- aching muscles
- irritability/loss of appetite.

The following may be serious side effects and you, or your child, may need urgent medical attention. However, these side effects are rare.

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

- tingling or numbness.

The following are very serious side effects and you, or your child, may need urgent medical attention or hospitalisation. All of these side effects are rare.

If any of the following happen to you or your child, tell your doctor immediately or go to Accident and Emergency 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, including convulsion associated with fever
- bleeding or bruising more easily than normal
- little or no urine
- severe stabbing or throbbing nerve pain
- neck stiffness, headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, and sensitivity to light.

Very rarely, a serious disorder called Guillain-Barré syndrome (GBS) may occur. GBS is an autoimmune syndrome caused by your body's own immune system. GBS may make you feel weak; you may have difficulty moving around or you may experience numbness and tingling in your limbs.

Other side effects not listed may occur in some people. Tell your doctor, nurse or pharmacist if you or your child 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 packaging.

Product description

What it looks like

Fluvax® vaccine is supplied in a pre-filled disposable syringe (with an attached needle) for single use only. Your doctor or nurse will give you or your child the injection.

The syringe is supplied in a blister pack inside a cardboard carton. The cardboard carton may contain one or ten syringes.

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 2018.

Other ingredients

- Sodium chloride
- Dibasic sodium phosphate anhydrous
- Monobasic Sodium phosphate
- Potassium chloride
- Monobasic Potassium phosphate
- Calcium chloride

Fluvax® vaccine may also contain trace amounts of detergent (sodium taurodeoxycholate), egg protein (ovalbumin), sucrose, neomycin, polymyxin B sulphate and propiolactone.

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

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

Name and Address of Sponsor

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