

Fluvax® Junior*Inactivated Influenza Vaccine (Split Virion)***Consumer Medicine Information****What is in this leaflet**

This leaflet answers some common questions about Fluvax Junior 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 your child having Fluvax Junior 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 Junior vaccine is used for

Fluvax Junior vaccine is used in children aged 6 months to 35 months. It 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 Junior vaccine contains fragments of three different types of influenza virus. Each year the Australian Influenza Vaccine Committee decides which three types of virus are most suitable.

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

Note: the vaccine will not protect your child from the other influenza viruses that Fluvax Junior vaccine does not contain.

Fluvax Junior vaccine is available only with a doctor's prescription. This year (2010) the viruses are A/California/7/2009 (H1N1) - like strain, A/Perth/16/2009 (H3N2) - like strain and B/Brisbane/60/2008 - like strain.

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

How Fluvax Junior vaccine works

Fluvax Junior vaccine works by causing your child's body to protect itself against infection by the influenza viruses, types A and B, that are in the vaccine. The body makes substances, called antibodies. Antibodies fight the influenza virus. If your child has been vaccinated, when your child comes into contact with the influenza viruses killed to make the vaccine, your child's body is usually able quickly to destroy the virus. This prevents your child from getting influenza.

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

If your child is being vaccinated for the first time against influenza, or your child has low immunity, protection requires two injections of Fluvax Junior vaccine. Your doctor will tell you if you or your child needs 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 Junior vaccine is very small. Whereas, the risks from not being vaccinated against influenza may be very serious.

Before your child is given Fluvax Junior vaccine**When your child must not be given Fluvax Junior vaccine**

Do not give Fluvax Junior vaccine if your child has or previously had an allergy to:

- Fluvax vaccine or Fluvax Junior vaccine or any of the ingredients listed at the end of this leaflet
- eggs
- 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 give Fluvax Junior vaccine if your child has a temperature higher than 38.5°C.

Fluvax Junior vaccine is not recommended for use in children under 6 months.

Do not give Fluvax Junior vaccine after the expiry date printed on the pack.

The Fluvax Junior vaccine syringe is supplied encased with 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.

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

Before your child is given Fluvax Junior vaccine

Tell your doctor if in the past your child 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 your child has an infection or high temperature.

Your doctor may decide to delay vaccination until your child's 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 your child has 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-Barre Syndrome (GBS), an illness which affects the nervous system and causes paralysis.

Tell your doctor if your child has allergies to:

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

Taking other medicines

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

Some medicines and Fluvax Junior vaccine may interfere with each other.

The following medicines or treatments may affect how well Fluvax Junior vaccine works:

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

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

Having other vaccines

Tell your doctor if your child has had any vaccines in the last 4 weeks.

Your doctor will tell you if Fluvax Junior 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 your child is given Fluvax Junior vaccine.

How Fluvax Junior vaccine is given

Fluvax Junior vaccine is given by injection by a doctor or nurse. In babies, Fluvax Junior vaccine is usually given in the upper thigh. Otherwise, it may be injected into the upper arm. Your doctor or nurse may choose to give it elsewhere.

Fluvax Junior vaccine should not be injected directly into a blood vessel.

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

How much is given

Fluvax Junior vaccine is given as one injection of 0.25 mL. If your child is being given Fluvax Junior vaccine for the first time, or your child has low immunity, it is recommended a second (booster) injection be given 4 weeks after the first injection.

Overdose is unlikely as your doctor or nurse gives your child 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 Junior 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.

If you miss an injection

If your doctor has recommended a second injection of Fluvax Junior vaccine and it has been missed, talk to your doctor.

After having Fluvax Junior vaccine

Things you must do for your child

Keep an updated record of your child's vaccinations.

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

It is important to have your child's second injection of Fluvax Junior 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 your child has developed protection (antibodies) against influenza.

If your child develops any medical problems after being given Fluvax Junior vaccine, tell your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if your child feels unwell after having Fluvax Junior vaccine.

Fluvax Junior 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. 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 seizures/convulsions in children under 5 years of age. Your doctor will assess and advise if it is appropriate for your child to receive the 2010 Southern Hemisphere influenza vaccine, depending on your child's underlying medical condition which in turn could lead to severe complications from influenza or spread influenza to other people.

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

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

- reaction around the injection site such as redness, burning, itchiness, tenderness, pain or discomfort, warmth 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 diarrhoea
- soreness, aching muscles or joints, muscle tenderness or weakness
- loss of appetite, irritability or teething.

These are the more common side effects of Fluvax Junior 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
- severe stabbing or throbbing nerve pain
- tingling, numbness or weakness.

These may be serious side effects. 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, including convulsion associated with fever
- 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 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-Barre syndrome may occur. This affects the nervous system and causes paralysis.

These are very serious side effects. 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 doctor or nurse if you notice anything that makes your child feel unwell.

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

Your child may not experience any of them.

Storing Fluvax Junior vaccine

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

If you need to store Fluvax Junior vaccine:

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

Fluvax Junior vaccine should not be used after the expiry date on the label.

Product description

What it looks like

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

Ingredients

Active ingredients:

Purified, inactivated virus fragments from influenza types:

- H1N1 strain - 7.5 micrograms
- H3N2 strain - 7.5 micrograms
- B strain - 7.5 micrograms

for the Southern Hemisphere winter season 2010.

Other ingredients

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

Fluvax Junior vaccine may also contain trace amounts of egg proteins, neomycin, polymyxin, sucrose and detergent (sodium taurodeoxycholate).

Fluvax Junior 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 Junior vaccine.

Manufacturer/ Distributor/ Supplier

Fluvax Junior vaccine is made in Australia by: CSL Limited,

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

Distributor

Fluvax Junior vaccine is distributed in Australia by:

CSL Biotherapies Pty Ltd,
ABN 66 120 398 067
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