Panvax® H1N1 Vaccine / Panvax® H1N1 Vaccine Junior

H1N1 Pandemic influenza vaccine (split virion, inactivated)

Consumer Medicine Information

What is in this leaflet

The information provided in this leaflet applies to Panvax® H1N1 Vaccine and Panvax® H1N1 Vaccine Junior, except where differences are indicated.

This leaflet answers some common questions about Panvax® H1N1 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 has weighed the risks of you, or your child, having Panvax® H1N1 Vaccine against the benefits they expect it will have for you.

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 Panvax® H1N1 Vaccine is used for

Panvax® H1N1 Vaccine is used in adults, adolescents and children from 6 months of age. It helps prevent influenza caused by the pandemic (H1N1) 2009 influenza virus, often called "the swine flu". Influenza is caused by infection with specific influenza viruses. New types of influenza virus can appear each year. In 2009, a new H1N1 influenza virus appeared that is the cause of the current pandemic. Panvax® H1N1 Vaccine contains purified fragments of the pandemic (H1N1) 2009 influenza virus.

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

Note: the vaccine will not protect you, or your child, from the other influenza viruses that Panvax® H1N1 Vaccine does not contain.

How it works

Panvax® H1N1 Vaccine works by causing your body to produce its own protection (antibodies) against the fragments of killed virus in the vaccine. These antibodies may help your immune system to destroy the virus if you later come into contact with it. This prevents you from getting pandemic influenza.

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

As with any vaccine, Panvax® H1N1 Vaccine may not fully protect everyone who gets the vaccine.

The chance of having a severe unwanted reaction after having Panvax® H1N1 Vaccine is very small. Whereas, the risks from not being vaccinated against pandemic influenza may be very serious.

Before you are given Panvax® H1N1 Vaccine

When you, or your child, must not be given the vaccine

You must not be given Panvax® H1N1 Vaccine if you have an allergy or have had an allergic reaction to:

- any of the ingredients listed at the end of this leaflet
- thiomersal (only for the vaccine in vials)
- eggs
- the antibiotics neomycin or polymyxin
- a previous injection with another flu vaccine

Symptoms of an allergic reaction may include:

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

You must not be given Panvax® H1N1 Vaccine if you have a temperature higher than 38.5°C.

Panvax® H1N1 Vaccine is not recommended for use in children under 6 months of age.

If you are not sure whether you, or your child, should have Panvax® H1N1 Vaccine, talk to your doctor, nurse or pharmacist.

Before you, or your child, are given Panvax® H1N1 Vaccine

Tell your doctor if you, or your child, have reacted to previous 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.

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 intend to become pregnant.
Your doctor will discuss the possible risks and benefits of having Panvax® H1N1 Vaccine during pregnancy.

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 Panvax® H1N1 Vaccine may interfere with each other.

The following medicines or treatments may affect how well Panvax® H1N1 Vaccine works:

- medicines which lower the immune system or affect the body's immune response, such as steroid tablets or some treatments for cancer.

Your doctor, nurse or pharmacist will advise you and decide whether or not to give the vaccine.

How Panvax® H1N1 Vaccine is given

When it is given

Panvax® H1N1 Vaccine is to be given to help prevent influenza disease caused by the pandemic (H1N1) 2009 influenza virus.

How it is given

Panvax® H1N1 Vaccine is given as an injection, usually into your upper arm muscle by a doctor or nurse. In babies, Panvax® H1N1 Vaccine Junior is usually given in the upper thigh. Your doctor or nurse may choose to give it elsewhere.

Panvax® H1N1 Vaccine should be given at facilities able to manage any allergic reaction. Allergy to influenza vaccine is uncommon, but allergy to any vaccine may occur.

How much is given

For adults, adolescents and children from 10 years of age, Panvax® H1N1 Vaccine is given as a single 0.5 mL (15 micrograms) injection.

For children from 3 years to 9 years of age, Panvax® H1N1 Vaccine is given as two 0.5 mL (15 micrograms) injections, with the second injection given at least four weeks after the first.

For children from 6 months to 35 months of age, Panvax® H1N1 Vaccine Junior is given as a two 0.25 mL (7.5 micrograms) injections, with the second injection given at least four weeks after the first.

Overdose is unlikely as your doctor or nurse gives you the injection.

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

After having Panvax® H1N1 Vaccine

Things you must do

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

If you, or your child, develop any medical problems after being given the vaccine, tell your doctor.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you, or your child, do not feel well after having the vaccine.

Panvax® H1N1 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.

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

The following are the more common side effects of seasonal influenza vaccination and some have been observed with Panvax® H1N1 Vaccine. Most of these are mild and short-lived.

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

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

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 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, 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
- bleeding or bruising more easily than normal
- little or no urine
- severe stabbing or throbbing nerve pain, neck stiffness

Very rarely, a serious disorder called Guillain-Barre syndrome (GBS) may occur. Guillain-Barre 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 above may occur in some people. Tell your doctor, nurse or pharmacist if

you notice anything that is making 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 Panvax® H1N1 Vaccine

Panvax® H1N1 Vaccine will be stored at the doctor's surgery or clinic. You do not need to store the vaccine yourself.

Product description

What it looks like

Panvax® H1N1 Vaccine is a clear to slightly opaque liquid in a glass vial or syringe. Your doctor or nurse will give you the injection.

Ingredients

Active ingredients:
Purified, inactivated virus fragments from influenza type:

- Pandemic (H1N1) 2009 influenza virus strain, 15 micrograms (0.5 mL dose) or 7.5 micrograms (0.25 mL dose)

The multi-dose vial contains thiomersal as a preservative. Pre-filled syringes are thiomersal-free. Multi-dose vials and pre-filled syringes do not contain latex.

Other ingredients:

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

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

The 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 Panvax® H1N1 Vaccine.

Manufacturer/ Distributor/ Supplier

Panvax® H1N1 Vaccine is made in Australia by:
CSL Limited, ABN 99 051 588 348
45 Poplar Road
Parkville
Victoria 3052
AUSTRALIA

Distributor

Panvax® H1N1 Vaccine is distributed in Australia by:
CSL Biotherapies Pty Ltd
ABN 66 120 398 067
45 Poplar Road
Parkville
Victoria 3052
AUSTRALIA

Registration number

AUST R 163897 (10 mL vial)
AUST R 165345 (5 mL vial)
AUST R 163900 (0.5mL pre-filled syringe)
AUST R 166312 (0.25 mL pre-filled syringe)

Date of preparation

3 December 2009