

PANVAX[®] INFORMATION SHEET

PANDEMIC H1N1 INFLUENZA VACCINE (UNADJUVANTED)

FOR PREGNANT WOMEN

November 4, 2009

Be sure to read this entire sheet thoroughly before receiving the Panvax[®] vaccine.

What is influenza and Pandemic H1N1 influenza?

Influenza (commonly known as "the flu") is a respiratory infection that is caused by a virus. People with influenza quickly become ill with a cough, fever, chills, sore throat, headache, muscle aches and tiredness. Most people are sick for 2 to 7 days, although the cough may last for weeks. In a few people, influenza can lead to pneumonia, hospitalization and even death. Influenza spreads easily from infected people to others through coughing and sneezing. It can also be picked-up through direct contact with surfaces and objects, like unwashed hands and toys.

Pandemic H1N1 influenza is a new influenza strain that emerged in April 2009. It has since spread around the world. Pandemic H1N1 influenza can infect anyone, although people younger than 60 years of age are more likely to become infected than older individuals. Most people recover uneventfully but a few people can develop serious complications. Those at a somewhat increased risk of complications when they get infected are children less than 5 years of age, people with other medical problems, pregnant women and women who had a baby in the past four weeks, people who are very overweight, Aboriginal people and seniors.

How does the Panvax[®] vaccine work?

Panvax[®] is an influenza vaccine made specifically to protect against the Pandemic H1N1 influenza strain. It comes from Australia and is made exactly like the seasonal influenza vaccine that is produced each year in that country. The vaccine contains inactivated virus that allows the body to make protection (also called an immune response) to the Pandemic H1N1 virus. This protection helps prevent the vaccinated person from getting sick if exposed to the virus. Based on early studies, Panvax[®] is expected to be very effective in preventing Pandemic H1N1 infection. Panvax[®] does **not** contain an adjuvant ("helper" substance) which is used in another Pandemic H1N1 influenza vaccine in Canada.

Panvax[®] will **not** protect against seasonal influenza infection. So, this year you will need both the Pandemic H1N1 and seasonal influenza vaccines to get as much influenza protection as possible.

Who should get Panvax[®] and how often?

Panvax[®] is being provided specifically for pregnant women. Only one dose is needed.

What are the risks from Panvax[®]?

Panvax[®] is made exactly like the seasonal influenza vaccine that is produced each year in Australia. Panvax[®] has not been specifically studied in pregnant women, however the seasonal vaccine is used in pregnant women with no safety concerns. This seasonal influenza vaccine is very safe and serious side effects are very rare, and Panvax[®] is expected to be just as safe.

Because the influenza vaccine does not contain live virus, you cannot get flu from the vaccine. Minor side effects from Panvax[®] are expected to include: pain and swelling where the injection is given, tiredness, headache, muscle pain, and fever. It is expected that most side effects will be mild, not last long and go away on their own.

Panvax[®] has not yet been used for a long time, but it is expected to be like the seasonal influenza vaccine where:

- Serious allergic reactions are very rare.
- An illness called Guillain-Barré Syndrome (GBS), which causes muscle paralysis, occurred after the influenza vaccine in 1976 and may occur very uncommonly after the seasonal influenza vaccine in some other influenza seasons.
- During the 2000-2001 influenza season, an "Oculo-Respiratory Syndrome" (ORS) was reported after the seasonal influenza vaccine. ORS began within 24 hours after vaccination and was generally mild. Symptoms included red eyes, coughing, wheezing, and/or swelling of the face.

Who should not get Panvax®?

- Anyone who has had a serious allergic reaction to:

- eggs or egg products;
- a previous influenza vaccine;
- neomycin;
- polymyxin B sulfate (found in Polysporin™);
- thimerosal (a form of mercury found in other vaccines and contact lens solution).

People who developed hives, swelling of the mouth or throat, or trouble breathing after a previous influenza vaccine, after eating eggs or egg products, or after receiving polymyxin B, neomycin or thimerosal, should not be vaccinated. They should consult with their doctor and consider seeing an allergist.

- Tell the nurse or doctor if you have ever had an allergic reaction to any vaccine in the past.
- Children under 10 years of age.
- People who are seriously ill with an infection that started recently should wait until they recover before getting Panvax®.
- People who have had severe Oculo-Respiratory Syndrome (ORS) after a past influenza vaccine that required them to be in the hospital.
- People with a history of Guillain-Barré Syndrome that developed within 8 weeks of a past influenza vaccine.

- People with bleeding disorders or who are taking medication that could affect blood clotting should mention this to the nurse before receiving the vaccine.

Some general information about being vaccinated:

- Wearing a short sleeve shirt makes it easier for you to get your vaccine.
- You will be asked to wait in the clinic area for at least 15 minutes after the needle is given.
- Panvax® will not prevent seasonal influenza so you will want to get your seasonal influenza vaccine as well for complete influenza protection. The seasonal and Pandemic H1N1 influenza vaccines can be given at the same visit or at any time before or after each other.
- Older children / adolescents can consent to their own vaccinations if they are able to understand the benefits and risks of receiving and not receiving the vaccine.
- There is no cost for the vaccination.

Be sure to read this entire sheet thoroughly before receiving the Pandemic H1N1 influenza vaccine, Panvax®. If you have any questions about influenza or Panvax®, please discuss them with the nurse before receiving your vaccine.