

# AREPANRIX™ INFORMATION SHEET

## PANDEMIC H1N1 INFLUENZA VACCINE (ADJUVANTED)

November 15, 2009

**Be sure to read this entire sheet thoroughly before receiving the Arepanrix™ 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 six weeks, people who are very overweight, Aboriginal people and seniors.

### **How does the Arepanrix™ vaccine work?**

Arepanrix™ is an influenza vaccine made specifically to protect against the Pandemic H1N1 influenza strain. It is made exactly like the seasonal influenza vaccine that is produced each year, except for the addition of a "helper substance" called an "adjuvant". The "adjuvant" is a substance added to the vaccine to "help" the body make good protection (also called an immune response) against Pandemic H1N1 infection. This protection or immune response helps prevent the vaccinated person from getting sick if exposed to the Pandemic H1N1 virus. Using the helper adjuvant means a smaller amount of vaccine can be given with each injection. Based on early studies, Arepanrix™ is expected to be very effective in preventing Pandemic H1N1 infection.

Arepanrix™ 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 the Arepanrix™ and how many doses do they need?**

Pandemic H1N1 influenza vaccination is recommended for anyone six months of age and older who needs or wants protection against Pandemic H1N1 influenza infection. There is another Pandemic H1N1 influenza vaccine that is available for pregnant women that does not contain the adjuvant.

To ensure a good immune response, two doses at least 21 days apart are needed in the following groups:

- All children 6 months to less than 3 years of age;
- Children 3 years to less than 10 years of age with underlying medical problems.

Healthy children 3 years to less than 10 years of age, and anyone 10 years of age and older, only require one dose.

### **What are the risks from Arepanrix™?**

Arepanrix™ is made exactly like the seasonal influenza vaccine that is produced each year, except for the addition of the helper "adjuvant". The seasonal influenza vaccine is very safe and serious side effects are very rare, and Arepanrix™ is expected to be just as safe. The adjuvant has been thoroughly studied in about 40,000 people and it has not been shown to cause any serious side effects. It should be noted that no pregnant women and few children less than 3 years of age were involved in the studies.

Because the influenza vaccine does not contain live virus, you cannot get flu from the vaccine. Minor side effects from Arepanrix™ are expected to include: pain and swelling where the injection is given, tiredness, muscle and joint pain, and headaches. Children may have a mild fever, be tired and irritable and not want to eat. As with the seasonal influenza vaccine, it is expected that most side effects will be mild, not last long and go away on their own.

Arepanrix™ 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. Some of these symptoms may be noted after the influenza vaccine.

### **Who should not get Arepanrix™?**

- Anyone who is seriously allergic to:
    - a previous influenza vaccine;
    - eggs or egg products;
    - 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 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.
  - Infants younger than 6 months of age.
  - People who are seriously ill with an infection that started recently should wait until they recover before getting Arepanrix™.
  - 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 discuss their medical situation with the nurse before receiving the vaccine.
  - Pregnant women can receive Arepanrix™ but the preferred product is the unadjuvanted Pandemic H1N1 influenza 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.
- Children who need a second dose in 21 days should check our web site at [www.healthunit.com/h1n1info](http://www.healthunit.com/h1n1info) or call 519-663-5317 ext. 2330 for available clinics.
- Arepanrix™ will not prevent seasonal influenza so you will want to get your seasonal influenza vaccine as well for complete influenza protection.
- 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, Arepanrix™. If you have any questions about influenza or Arepanrix™, please discuss them with the nurse before receiving your vaccine.**