



Health and Healthy Living
Public Health Division

Fact Sheet

Pandemic H1N1 Influenza Vaccine with Adjuvant¹ (Pandemic Flu Shot)

Manitoba is now in the second wave of the pandemic. A new flu shot for pandemic H1N1flu is now available for all Manitobans who need or want it and are expected to benefit from it.

Given the expectation of more severe illness this fall and winter, it is especially important for those at increased risk, and who would benefit most, to get their shot as soon as possible – before they are exposed to the virus.

This fact sheet provides important information about this pandemic flu shot and tries to answer the most common questions that people have been asking. As with any vaccine, getting the pandemic flu shot is a personal decision and is something you should feel free to discuss with a doctor or nurse.

The pandemic H1N1 influenza vaccine has been recommended for use in Canada by the Public Health Agency of Canada, after reviewing information and advice from the manufacturer, the regulator (Health Canada), international research and experience, vaccine experts of our national Pandemic Vaccine Task Group and provincial chief medical officers of health.

Studies have shown that 85 to 98 per cent of healthy adults who received this vaccine developed high levels of antibodies against the pandemic H1N1 flu. Health Canada has approved and licensed this vaccine and it has been recommended for use by the Public Health Agency of and the Society of Obstetricians and Gynecologists of Canada.

The following questions and answers are intended to provide you with the most current information about this pandemic flu shot. As new information becomes available, it will be posted on the flu website at manitoba.ca. Please check our website often to be sure you have the most up-to-date information.

What is the pandemic flu?

Pandemic H1N1 influenza is a new strain of the influenza virus that has been reported throughout the world. Its mild symptoms have been similar to those of seasonal flu. However, as with any type of flu, the pandemic H1N1 flu can cause severe illness and death.

Compared to seasonal flu- which causes complications and death primarily in senior citizens and the very young- this pandemic flu has caused more severe illness in people under 65 years of age- including people without previous medical conditions. Although most Manitobans who got pandemic flu in the first wave last spring did not require medical or hospital care, it is likely that the second wave this fall and winter could result in more severe illness, especially if people do not get the shot in time.

¹ Product name is Arepanrix™

What is the pandemic H1N1 influenza vaccine?

The pandemic H1N1 influenza vaccine is a shot (injection) that makes your immune system develop antibodies (immunity) against the pandemic influenza virus. The virus in the vaccine has been killed, so it cannot give you an actual infection and cannot give you pandemic flu.

Why is this vaccine being recommended?

- To cut down your chances of getting pandemic flu, especially those at higher risk for severe illness and death.
- To reduce the spread of pandemic flu.
- To reduce the need for hospitalization, especially intensive care.
- To reduce the number of people who have to stay home sick from work or school.
- To reduce spreading the virus to swine or poultry and to reduce the possibility of further mutation of the virus.

How well will the vaccine protect against pandemic H1N1 influenza?

Like other influenza vaccines, the pandemic H1N1 influenza vaccine with adjuvant is expected to provide protection within two weeks of being vaccinated. Studies have shown 85 to 98 per cent of healthy adults who received this flu shot developed high levels of antibodies.

Although no vaccine is 100 per cent effective, this flu shot is expected to work very well because it matches the pandemic H1N1 influenza virus that is now circulating.

However - In addition to getting this flu shot, it is important to remember to do other things to prevent spreading or getting the flu and to prevent severe illness and death:

- Cover your cough, wash your hands regularly, and limit touching your eyes, nose and mouth;
- Stay home when you are sick and don't return to work or school until you feel well enough to do so;
- See a doctor or nurse within 24 hours of getting symptoms of the flu if you have risk conditions for severe illness (ex. under five years of age, chronic medical condition, Aboriginal ancestry, pregnant) – you need to be assessed and you could be offered antiviral medication that works best the sooner it is taken;
- Get emergency medical care if you develop severe symptoms, especially shortness of breath or severe weakness.

Is the vaccine mandatory for anyone?

No. In Manitoba, all immunizations, including this flu shot, are voluntary and given only after informed consent.

Who is recommended to get this pandemic flu shot first in Manitoba? (not in any particular order of priority)

- Children aged six months to under five years old;
- Pregnant women more than half-way through their pregnancy;
- Anyone of Aboriginal ancestry (First Nations, Metis or Inuit);
- Disadvantaged individuals (ex. homeless, refugee, recent immigrant, poverty);
- People living in remote or isolated areas;
- People under 65 with a chronic medical condition or other risks, including severe obesity, substance abuse or alcoholism;

- Anyone with a weakened immune system or those who live with or care for them;
- Those who live with or care for infants under six months old;
- Single parents or anyone solely responsible for a dependent; and
- Health care workers and medical first responders.

Who else should get this flu shot?

- People who provide services that are critical to meeting the necessities of life and support the daily operation of Manitoba communities, particularly where there are limited numbers of people who can perform those jobs if someone becomes ill;
- People who work directly with swine and poultry;
- Any Manitoban (over six months of age) who needs or wants to be vaccinated and would be expected to benefit from the vaccine.

How safe is this vaccine?

As with all vaccines and medicines, this flu shot can cause side effects in some people and its effectiveness can vary. As with all vaccines, there is always some uncertainty about short-term and long-term effects, some of which cannot be known until the vaccine is used by many people and monitored over time. This may especially be true in a situation like this when a vaccine is manufactured and evaluated rapidly, by necessity, to prevent a new infectious disease.

Influenza vaccines without adjuvant have been used for many years in Canada and around the world for annual seasonal flu - their short term and long term safety record has been observed and studied for decades. The Public Health Agency has said that all evidence suggests that vaccines with adjuvant are just as safe as vaccines without adjuvant- however, there has been no safety data published for the use of this vaccine with adjuvant in pregnant women. There has also been limited data on use of this vaccine with adjuvant in young children under the age of three years. Another type of pandemic flu shot without adjuvant is expected to be available in Manitoba in November, which can be used for pregnant women and children between six months and three years of age (see below).

Should this vaccine with adjuvant be used for pregnant women and children?

Since there has been no safety data published on the use of this flu shot with adjuvant in pregnant women, the Public Health Agency of Canada has recommended that pregnant women should receive the pandemic flu shot without adjuvant. The Public Health Agency of Canada has also recommended that if the pandemic flu shot without adjuvant is not available and pandemic H1N1 influenza rates are high or increasing, women who are more than 20 weeks pregnant should be offered the pandemic flu shot with adjuvant. Pregnant women may wish to talk to their health care provider about which pandemic flu shot is best for them.

The pandemic flu shot with adjuvant has been recommended as the preferred pandemic H1N1 flu vaccine for children and all non-pregnant adults because it is expected to be more effective in boosting the immune system and preventing pandemic flu. For parents/guardians who are concerned about using this vaccine for their young children, the pandemic flu shot without adjuvant may be considered for children six months to three years. Parents/guardians can talk to their child's doctor to find out more.

The following people should NOT get this pandemic flu shot unless it has been recommended by their doctor and can be given under close medical supervision?

- Anyone who has a high fever or who has an uncontrolled bleeding or bruising problem at the time of vaccination.
- Infants under six months of age (not licensed for this use);
- People who are hypersensitive (allergic) to eggs (ex. hives, swelling of mouth and/or throat or breathing difficulty);
- People who have had a previous severe allergic reaction to any influenza vaccine or any substance that is in the vaccine;
- People who have had Guillain-Barré Syndrome within eight weeks of receiving any vaccine;
- People who have had a lab-confirmed case of pandemic H1N1 influenza;
- Pregnant women less than 20 weeks along in their pregnancy.

What is in the vaccine?

- Killed pandemic H1N1 influenza virus
- Thimerosal (organic mercury) preservative
- Trace amounts of egg protein and formaldehyde
- An adjuvant containing three substances to boost the body's immune response: squalene (a natural protein extracted from shark livers) – α -tocopherol (vitamin E), and polysorbate 80 (commonly found in ice cream and cosmetics).

What are possible side effects?

As with all medicines, this pandemic flu shot can cause side effects. These side effects have been observed to be similar to those of seasonal flu shots that do not contain an adjuvant, except for higher rates of some side effects especially local reactions such as pain at the injection site.

Rare side effects of seasonal influenza vaccines have included Guillain-Barré syndrome, which is a form of paralysis that may be temporary or permanent. This has been estimated to occur at one in every one million vaccinations. Severe allergic reactions (anaphylaxis -which can be life-threatening) have also been known to occur in approximately one in every one million vaccinations in Canada. As with any new vaccine, long-term effects are currently unknown.

The Public Health Agency has stated that the expected side effects are:

Very common: (more than 10 per cent of all vaccinations) – headache; tiredness; pain; a hard lump at the injection site; joint pain.

Common: (between one and 10 per cent of all vaccinations) - warmth, itching or bruising at the injection site; increased sweating/shivering, flu-like symptoms; swollen glands in the neck, armpit or groin.

Uncommon: (between 0.1 to one per cent of vaccinations) - tingling or numbness of the hands or feet; sleepiness; sleeplessness; dizziness; diarrhea; vomiting; stomach pain; feeling sick; itching.; or rash.

These side effects have usually disappeared within one to two days without treatment. If they persist, people should consult with their health care provider

How is the vaccine given?

The current recommendations are:

- Manitobans 10 years and older should receive one dose of this pandemic flu vaccine with adjuvant.
- Children from six months to nine years should receive this pandemic flu vaccine with adjuvant in two half-doses, given at least 21 days apart.

This pandemic flu shot should be given with a needle into the muscle of the upper arm. For infants (six to 11 months), it should be given in the upper thigh. It can be given anytime before, at the same time as (in a separate limb), or anytime after the seasonal flu shot or any other vaccination.

Recommended Resources

For a complete list of medicinal and non-medicinal ingredients and other technical information about this vaccine, please see the adjuvanted pandemic H1N1 influenza vaccine product leaflet available at: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/interimorders-arretesurgence/prodinfo-vaccin-eng.php>

Government of Manitoba: www.manitoba.ca

Public Health Agency of Canada- FightFlu.ca: www.FightFlu.ca

Canadian Coalition for Immunization Awareness & Promotion – Canadian Public Health Association: www.immunize.cpha.ca

Information about your immunization will be recorded in the Manitoba Immunization Monitoring System (MIMS) and used for surveillance by Manitoba Health and Healthy Living to produce immunization records, monitor vaccine uptake, how well vaccines are working, and may also be used for research. All information recorded in MIMS will be protected in accordance with the Protection of Privacy provisions of *The Personal Health Information Act*.

If you want further information, contact your health care provider, your local public health unit or nursing station, or call Health Links-Info Santé at 788-8200 in Winnipeg or toll-free at 1-888-315-9257.