

Fact Sheet- Pandemic H1N1 Influenza Vaccine (H1N1 Flu Shot) with Adjuvant: Product Name: Arepanrix™

The following questions and answers are intended to provide you with the most current information about this H1N1 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 H1N1 flu vaccine with adjuvant?

The pandemic H1N1 influenza vaccine with adjuvant is a shot (injection) that makes your immune system develop antibodies (immunity) against the H1N1 flu virus. The virus in the vaccine has been killed, so it cannot give you an actual infection and cannot give you pandemic flu. The vaccine contains an adjuvant, which is a substance that boosts an individual's immune system and increases their response to a vaccine.

How well will this vaccine protect against pandemic H1N1 flu?

Like other influenza vaccines, the pandemic H1N1 flu shot with adjuvant is expected to provide protection within two weeks of being vaccinated. In a study of healthy adults between 18 and 60 years of age the H1N1 flu shot with adjuvant produced protective levels of antibody (immunity) in 98 to 100 per cent of people. The same study showed that the H1N1 flu shot without adjuvant produced protective levels of antibody in 94 per cent of people participating in the study. So both the H1N1 flu vaccine with adjuvant and the vaccine without adjuvant provide a strong immune response in over 90 per cent of people who received it.

Is this vaccine mandatory for anyone?

No. In Manitoba, all immunizations, including this H1N1 flu shot, are voluntary and given only after informed consent.

Who should get this vaccine?

The H1N1 flu shot with adjuvant has been recommended for children and all non-pregnant adults, including women who are breastfeeding, because it contains a "booster" element (adjuvant) that increases a person's immune response to the vaccine. However, people aged 10 to 64 years with healthy immune systems may also consider the H1N1 flu shot without adjuvant because it is also expected to provide a good immune response in this population.

The vaccine with adjuvant continues to be the preferred choice for children between the ages of six months and under 10 years of age, adults 65 years of age and over and people with weakened immune systems. This is because preliminary data suggests that the vaccine without adjuvant is less effective in producing an immune response and preventing H1N1 flu in people in these groups.

Should this vaccine be used for pregnant women?

Immunization is the most effective way to prevent illness and protect your baby's health. The Public Health Agency of Canada has recommended that pregnant women at any stage of their pregnancy should receive the H1N1 flu shot without adjuvant. Although there is no evidence that the H1N1 flu shot with adjuvant is unsafe for pregnant women, this kind of vaccine hasn't been tested in pregnant women. The H1N1 flu shot without adjuvant has not been tested in pregnant women either, but vaccine without adjuvant is made the same way as the regular seasonal flu shot, which has been used safely in pregnant women for many years. So vaccine without adjuvant is the first choice for pregnant women.

The agency has also advised that if the H1N1 flu shot without adjuvant is not easily available and pandemic H1N1 flu rates are high or increasing, women who are more than 20 weeks pregnant or women at any stage of pregnancy who have a chronic medical condition (like asthma or diabetes) can consider getting the H1N1 flu shot with adjuvant. Women who are less than 20 weeks pregnant and are healthy should wait to get the vaccine without adjuvant. Pregnant women can talk to their health care provider about which pandemic flu shot is best for them.

The following people should not get this H1N1 flu shot:

- Anyone who has a high fever 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)--*in some circumstances the vaccine may be given under close medical supervision*;
- 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 an influenza vaccine;

- People who have had a lab-confirmed case of pandemic H1N1 flu do not need the pandemic flu shot (people who have had flu symptoms but have not had a lab-confirmed case should still get the shot).

How is this vaccine given?

The current recommendations are:

- Manitobans 10 years and older and healthy children from three to nine years of age should receive one dose of this H1N1 flu vaccine with adjuvant.
- Children from six months to less than three years and children from three to nine years of age with chronic health conditions should receive this H1N1 flu vaccine with adjuvant in two half-doses, given at least 21 days apart.

This H1N1 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.

What is in this vaccine?

- Killed pandemic H1N1 flu 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 H1N1 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.

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.

In past influenza seasons some individuals experienced one or more of the following symptoms associated with oculorespiratory syndrome (ORS): red eyes, shortness of breath, chest tightness, cough, sore throat or swelling of part or all of the face. These signs and symptoms usually appeared within 24 hours of immunization and disappeared within two days.

Rare side effects of seasonal flu shots 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- (i.e. anaphylaxis -which can be life-threatening) have also been known to occur (one in every 100,000-1,000,000 vaccinations in Canada). As with any new vaccine, long-term effects are currently unknown. People who experience a severe reaction should call 911 or seek immediate medical care.

People who have concerns about a serious or unexpected side effect, have severe pain, or need advice on how to manage a side effect, should contact their health care provider or call Health Links-Info Santé at 788-8200 or 1-888-315-9257. Health care providers are required to report significant adverse events following immunization to monitor for vaccine safety.

Recommended Resources

- For a complete list of medicinal and non-medicinal ingredients please see the product leaflet. available through your immunization provider.
- 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

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