

Fact Sheet Pandemic H1N1 Influenza Vaccine (H1N1 Flu Shot) without Adjuvant: *GSK Product*

The following questions and answers are intended to provide you with the most current information about the 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 without adjuvant?

The pandemic H1N1 influenza vaccine 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 H1N1 flu vaccine without adjuvant is made in the same way as the annual seasonal flu vaccine.

How well will this vaccine protect against pandemic H1N1 flu?

Like other influenza vaccines, the pandemic H1N1 flu shot without 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 without adjuvant produced protective levels of antibody (immunity) in 94 per cent of people. The same study showed that the H1N1 flu shot with adjuvant produced protective levels of antibody in 98 to 100 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.

Although studies are ongoing with the H1N1 flu shot without adjuvant, the immune response in children, adolescents and people over 60 years of age has not been evaluated. Based on preliminary studies, young children and the elderly are expected to have a better immune response from the vaccine with adjuvant.

Is this vaccine mandatory for anyone?

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

Who should get this vaccine?

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. The vaccine is also available to people aged 10 to 64 years with healthy immune systems because it is expected to provide a good immune response in this population.

However, at this time, the H1N1 flu shot **with adjuvant** (Arepanrix™) continues to be the preferred option for use in:

- 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.

The following people should NOT get this pandemic flu shot:

- Anyone who has a high fever at the time of vaccination;
- Children under six months of age;
- 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).

The H1N1 flu shot can be given to people who have a bleeding disorder or are taking oral blood thinners. However, for those people who receive treatment for their disorder, the shot should be given after treatment and on the same day.

How is this vaccine given?

This H1N1 flu shot should be given with a needle into the muscle of the upper arm. 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
- Very small amounts of egg protein, formaldehyde, sodium deoxycholate and sucrose (sugar).

What are possible side effects?

As with all medicines and vaccines, the H1N1 flu shot can cause side effects. These side effects have been observed to be similar to those of seasonal flu shots.

Side effects that may occur with this vaccine include:

Common: pain; reddening or swelling at the injection site; feeling unwell; fever; swelling of the lymph glands.

Less common: headache; shivering; sweating; tiredness; muscle and/or joint aches.

These side effects usually disappear 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 also 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 and other technical information about this vaccine, 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