

**INFLUENZA A (H1N1) 2009 PANDEMIC
MONOVALENT VACCINE (without adjuvant)**
from GlaxoSmithKline Inc. (GSK)
FACT SHEET



What is Pandemic H1N1Influenza?

Influenza (the flu) is a serious respiratory infection that is caused by a virus. Influenza causes fever, cough, headache, muscle soreness, sore throat and stuffy nose. 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 appeared 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 fully; 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 Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (without adjuvant) work?

The vaccine is an influenza vaccine made specifically to protect against the Pandemic H1N1 influenza strain. It is made in Canada and is like Fluviral[®], a seasonal influenza vaccine that is produced each year. 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, this vaccine is expected to be very effective in preventing Pandemic H1N1 infection. Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (without adjuvant) does **not** contain an adjuvant ("helper" substance) which is used in the other Pandemic H1N1 influenza vaccine in Canada.

Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (without adjuvant) 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 this vaccine and how often?

This vaccine is recommended for pregnant women at any stage of pregnancy and healthy people 10 to 64 years of age who need protection against Pandemic H1N1 influenza infection. Only one dose of this vaccine is required.

What are the risks from Influenza A (H1N1) Pandemic Monovalent Vaccine (without adjuvant)?

This vaccine is made like Fluviral[®], the seasonal influenza vaccine that is produced in Canada each year. Fluviral is a very safe vaccine and serious side effects are very rare.

Because the influenza vaccine does not contain live virus, you cannot get the flu from the vaccine.

Minor side effects from the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine 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.

Experience with Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (without adjuvant) is limited, 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 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 INFLUENZA A (H1N1) 2009 PANDEMIC MONOVALENT VACCINE (WITHOUT ADJUVANT)?

- Anyone who has had a serious allergic reaction to:
 - eggs or egg products
 - a previous influenza vaccine
 - Thimerosal (a form of mercury found in other vaccines and contact lens solution)
 - Formaldehyde
- Tell the nurse or doctor if you have ever had an allergic reaction to any vaccine in the past.
- People who are seriously ill with an infection that started recently should wait until they recover before getting vaccinated.
- People who have had severe Oculo-Respiratory Syndrome (ORS) after a past influenza vaccine that required them to be in the hospital should consult their doctor.
- People with a history of Guillain-Barré Syndrome that developed within 8 weeks of a past influenza vaccine should consult their doctor.
- People with bleeding disorders or who are taking medication that could affect blood clotting should mention this to the nurse before receiving the vaccine.

Allergic reactions to the influenza vaccine are very rare. If a reaction to the vaccine was to happen, it would usually happen shortly after the vaccine is given. You must remain in the clinic area for at least 15 minutes after the needle is given.

Call your doctor if any of these symptoms happen within three days after your vaccination

- Hives
- Swelling of the mouth or throat
- Trouble breathing, hoarseness or wheezing
- Any other unusual or serious condition

If you have any questions or concerns about influenza immunization, please speak to the nurse

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