

# H1N1-2009 Influenza Virus

## Q & As

Updated 2009-11-26

Please note these Q & As include information that can be targeted to both healthcare professionals and the general public

### General Influenza Questions:

#### What is seasonal influenza (flu)?

Seasonal influenza (commonly known as “the flu”) is an acute respiratory illness caused by influenza A and B viruses and occurs in Canada every year, generally during late fall and the winter months. Influenza A viruses are the most common cause of annual influenza epidemics. Outbreaks of influenza B are generally more localized and in any year may be restricted to one region of the country.

#### What are the symptoms of influenza infection?

Influenza, in general, is an acute viral disease of the respiratory tract that is characterized almost always by cough and fever. Common symptoms also include: fatigue, muscle aches, sore throat, headache, decreased appetite, runny nose. Uncommon symptoms may include: nausea, vomiting, and diarrhoea. In most patients, recovery occurs within 2 to 7 days.

#### What is the pandemic H1N1-2009 virus?

The pandemic H1N1-2009 virus (H1N1-2009) is a novel (new) influenza virus causing illness in people. It is a triple reassortment virus, meaning that it contains genetic material from an avian influenza virus, two different swine viruses (a North American strain and a Eurasian strain) and a human influenza virus. It has never before circulated and is not related to previous or current human seasonal influenza viruses. Most people have no natural immunity to protect against this virus. The H1N1-2009 flu virus emerged in April 2009 and surveillance of its spread shows that it is affecting younger people more than seasonal flu, which most severely affects seniors and young children. People with underlying medical conditions and pregnant women are at greater risk of complications for from the H1N1 flu.

#### Is seasonal influenza different from the H1N1-2009 influenza?

The H1N1-2009 flu virus causes a respiratory illness that cannot be distinguished from seasonal flu. Pandemic influenza A H1N1-2009 is a new strain of influenza A; most people have limited to no immune protection, whereas influenza A or B strains (as seen in the seasonal influenza) are often the same as previous years or contain only minor variations. Many people have some immunity protection to seasonal influenza as a result of exposure in previous years. Most people born before 1957 are less susceptible to the pH1N1 virus.

#### Is “bird flu” (H5N1) different from the H1N1-2009 influenza?

Yes, the “bird flu” (H5N1) is different from pandemic H1N1-2009 influenza. Avian influenza, or “bird flu”, is an influenza infection that normally infects birds and, less commonly, pigs. Avian influenza viruses are highly species-specific, but have, on rare occasions, infected humans. Rare instances of limited human-to-human transmission of H5N1 and other avian influenza viruses have occurred in association with outbreaks in poultry.

## General Influenza Vaccine Questions:

### If I had the seasonal influenza vaccine last year do I need to get the vaccine again this year?

Yes, because the seasonal influenza virus changes often, it is necessary to get a seasonal influenza immunization every year, for protection against the new virus strains that may be circulating that year. Adults need only one dose each year of the seasonal influenza vaccine to be protected against the virus.

### Which H1N1 vaccines are available in Ontario?

Ontario has procured three vaccines for H1N1-2009 immunization. The three H1N1-2009 vaccines currently available in Ontario are:

- Arepanrix™ – an adjuvanted vaccine manufactured by GlaxoSmithKine Canada (GSK)
- Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant – an unadjuvanted vaccine manufactured by GlaxoSmithKine Canada (GSK)
- Panvax® – (for pregnant women only) - an unadjuvanted vaccine manufactured by CSL Limited, Australia

Information about which recipients should receive which H1N1 vaccine is available in the *Questions about the H1N1-2009 vaccine* section of this document.

### What are the risks from H1N1 Influenza Vaccine?

Serious effects from the vaccine are very rare. Most people have no problems after receiving an influenza vaccine. Possible side effects are as follows:

1. Redness, soreness and swelling where the needle was inserted which may last for 1 to 2 days.
2. Headache, fatigue, fever; these occur infrequently.
3. Allergic reactions like hives, wheezing, difficulty breathing or swelling of the face and mouth; these occur very rarely. If these reactions develop, see a doctor immediately.
4. An illness called Guillain-Barré Syndrome (GBS), which causes muscle paralysis, occurred after the influenza vaccine used in 1976 and may occur very uncommonly after the seasonal influenza vaccine in some other influenza seasons.
5. In 2001, "Ocular-Respiratory Syndrome" (ORS) was reported after the seasonal influenza vaccine was administered. ORS began 24 hours after vaccination and was generally mild; symptoms included red eyes, cough, wheezing, and/or swelling of the face.

If you experience any of the above effects please contact your local physician or visit your local urgent care clinic or emergency department.

Be sure to keep your personal immunization record up-to-date when you receive the vaccine. Carry this record (influenza immunization card) with you should you become ill and see a doctor or attend a clinic or hospital so they will know that you have had the seasonal influenza vaccine, and one or two doses of the H1N1-2009 vaccine and the date the vaccine(s) was given.

## Questions about the H1N1-2009 vaccine:

### Will the new H1N1-2009 vaccines be safe?

Licensed vaccines, including influenza vaccines, are held to a very high standard of safety. All precautions will be taken to ensure safety of new pandemic vaccines and results from clinical trials, both completed and currently ongoing or soon to be initiated, will be taken into consideration by the regulatory authorities in their decision to license pandemic vaccines.

### What are adjuvants? Are they safe?

Adjuvants are substances that are added to vaccines to help the body develop good protection/ immune response against pandemic H1N1 infection. Using an adjuvant means a smaller amount of the vaccine can be given with each injection. In early June, WHO held a consultation of experts which reviewed the safety of adjuvants. No significant safety concerns were identified in this consultation. Vaccine safety – including adjuvanted and non-adjuvanted vaccine - will be carefully monitored through post-marketing surveillance.

### How well does the H1N1-2009 vaccine protect against pandemic influenza?

Based on early studies, Arepanrix™ (manufactured by GSK) Panvax® (manufactured by CSL) and Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant (manufactured by GSK) are all expected to be a very effective vaccine to prevent H1N1 infection.

### How many doses of the H1N1-2009 vaccine will I need?

- o Children between 6 months to less than 3 years of age require 2 pediatric doses of adjuvanted Arepanrix™ vaccine. The interval between doses should be a minimum of 21 days.
- o Children with chronic health conditions from the ages of 3 to 9 years may need a second dose of adjuvanted Arepanrix™ vaccine.
- o Most other people need only one dose of H1N1-2009 adjuvanted Arepanrix™ vaccine, or unadjuvanted Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant vaccine.
- o Pregnant women need one dose of unadjuvanted vaccine.

### What dose of H1N1 vaccine do I need, and which type of H1N1 vaccine should I have?

Please refer to the charts below for additional information about H1N1 vaccine and the appropriate recipients for each type of H1N1 vaccine currently offered in Ontario. Please note there are two charts; one for healthy individuals, and one for individuals with chronic health conditions. The information for those with \*\*chronic health conditions is highlighted in grey.

### I have a \*\*chronic health condition, but I am healthy and I *do not* have a weakened immune system, which type of H1N1 vaccine should I have?

Having a chronic condition does not always mean that someone has a weakened immune system. If an individual who is between the ages of 10 to 64 years has a chronic condition, and they *do not* have a weakened immune system; they can have either the unadjuvanted Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant, or the adjuvanted Arepanrix™ vaccine unless medically contraindicated.

Pregnant women can have either Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant, or Panvax® (for pregnant women only) vaccine.

### 1. Healthy Populations (with healthy immune systems): Recommended H1N1 Influenza Vaccine by Age and Dose

| AGE                   | NAME OF VACCINE                                                                                                                   | DOSE    | # OF DOSES | MINIMUM INTERVAL |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------|---------|------------|------------------|
| 0 to < 6 months       | n/a                                                                                                                               | n/a     | n/a        | n/a              |
| 6-months to < 3 years | Arepanrix™                                                                                                                        | 0.25 mL | 2          | 21 days          |
| 3 years to < 10 years | Arepanrix™                                                                                                                        | 0.25 mL | 1          | n/a              |
| 10 years to 64 years  | <ul style="list-style-type: none"> <li>Arepanrix™</li> <li>Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant</li> </ul> | 0.5 mL  | 1          | n/a              |
| 65 years and above    | Arepanrix™                                                                                                                        | 0.5 mL  | 1          | n/a              |
| Pregnant women***     | <ul style="list-style-type: none"> <li>Panvax®</li> <li>Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant</li> </ul>    | 0.5 mL  | 1          | n/a              |

### 2. Individuals with \*\*Chronic Health Conditions (and/or weakened immune systems): Recommended H1N1 Influenza Vaccine by Age and Dose

| AGE                   | VACCINE                                                                                                                        | DOSE    | # OF DOSES | MINIMUM INTERVAL |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------|---------|------------|------------------|
| 0 to < 6 months       | n/a                                                                                                                            | n/a     | n/a        | n/a              |
| 6-months to < 3 years | Arepanrix™                                                                                                                     | 0.25 mL | 2          | 21 days          |
| 3 years to < 10 years | Arepanrix™                                                                                                                     | 0.25 mL | 2          | 21 days          |
| 10 years to 64 years  | Arepanrix™                                                                                                                     | 0.5 mL  | 1          | n/a              |
| 65 years and above    | Arepanrix™                                                                                                                     | 0.5 mL  | 1          | n/a              |
| Pregnant women***     | <ul style="list-style-type: none"> <li>Panvax®</li> <li>Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant</li> </ul> | 0.5 mL  | 1          | n/a              |

#### \*\*Chronic Health Conditions:

Adults (including pregnant women) and children with the following chronic health conditions:

- cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma);
- diabetes mellitus and other metabolic diseases;
- cancer, immunodeficiency, immunosuppression (due to underlying disease and/or therapy);
- renal disease;
- anemia or hemoglobinopathy;
- conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration; or children and adolescents with conditions treated for long periods with acetylsalicylic acid.

### \*\*\*Pregnant Women

Unadjuvanted vaccine is considered the preferred option for pregnant women, given that there are extensive safety data on the use of unadjuvanted seasonal influenza vaccines in pregnant women and there are currently no data on the safety of the adjuvanted vaccine in this group. This recommendation is made as a precaution for this population, given the potential for concern that pregnant women may have about receiving a newly developed vaccine during their pregnancy. Unadjuvanted vaccine may be administered at any stage of pregnancy. The WHO's Strategic Advisory Committee of Experts (SAGE) has recommended that, if unadjuvanted product is not available, pregnant women should be vaccinated with another pandemic vaccine, such as an adjuvanted formulation. Therefore, if unadjuvanted vaccine is not available and if H1N1 influenza activity is increasing or high in a particular region of Canada, pregnant women with pre-existing health conditions and healthy pregnant women who are in the second half of pregnancy (e.g. above 20 weeks gestation) can be offered adjuvanted vaccine.

### Do I have to go back to the same place to get my 2<sup>nd</sup> dose of H1N1-2009 vaccine?

Please note that only children between the ages of 6 months to 3 years old, or children 3 to <10 years of age with a chronic medical condition require a second dose of H1N1-2009 vaccine.

No, you do not need to return to the same delivery location where you received your first dose of vaccine. You may go to any service delivery location identified by your local health unit to receive the second dose of H1N1-2009 vaccine. Make sure that you bring you/your child's influenza immunization card with you for each visit. It is recommended that the vaccine given as a second dose is the same as the first one (i.e. both first and second dose should be adjuvanted vaccine).

### Will this year's seasonal influenza vaccine also protect against the H1N1-2009 virus?

No, having been immunized with this year's seasonal influenza vaccine will not provide protection against the H1N1-2009 virus, but it will provide protection against circulating seasonal influenza viruses.

### Do I have to pay for the H1N1-2009 vaccine?

No. The pandemic influenza A H1N1-2009 vaccine is available free of charge to individuals who live, work and attend school in Ontario and Canada.

### Who should get H1N1-2009 vaccine?

It is recommended that all Canadians  $\geq 6$  months of age should receive H1N1-2009 vaccine unless medically contraindicated.

### Who should get the H1N1-2009 adjuvanted vaccine Arepanrix<sup>TM</sup>?

It is recommended that all Canadians, excluding pregnant women, who are  $\geq 6$  months of age should receive the H1N1-2009 adjuvanted vaccine Arepanrix<sup>TM</sup> unless medically contraindicated.

### Who should get the H1N1-2009 unadjuvanted vaccine?

- Pregnant women should get either of the unadjuvanted H1N1 vaccines (**Panvax®**, or **Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant**) unless medically contraindicated.
- As there is a small excess of unadjuvanted H1N1 vaccine, some healthy individuals who are between the ages of 10 and 64 years can have the GSK unadjuvanted product: Influenza A (H1N1) 2009 Monovalent Vaccine without adjuvant.

*At this time Panvax® vaccine can **only** be used for pregnant women.*

### **Who should get the Panvax® vaccine?**

*At this time Panvax® vaccine can **only** be used for pregnant women.* Canada has authorized access to Panvax® H1N1 vaccine to ensure that pregnant women are able to receive an unadjuvanted vaccine on a timely basis. In Canada, Panvax® vaccine has been specially acquired under interim order for use in pregnant women only. Based on the recommendations from the Public Health Agency of Canada, the Chief Public Health Officer (CPHO) has made recommendations about the storage of Panvax® vaccine under cold chain to allow the vaccine to be stored for 28 days instead of 24 hours, and this is the only additional allowance that the CPHO has made regarding the use of Panvax® vaccine. The product information leaflet regarding the use of Panvax® vaccine from CSL indicates the recommended use of Panvax vaccine in Australia only. In Canada Panvax® has been authorized under an interim order, and currently this interim order only allows the Panvax® vaccine to be administered to pregnant women.

### **Who should not get the H1N1-2009 unadjuvanted vaccine?**

Children under 10 years of age, and those 65 years of age and over, and those with chronic health conditions should not receive the unadjuvanted vaccines.

### **Why can't children under the age of 10 receive the H1N1-2009 unadjuvanted vaccine?**

This vaccine has not been studied in children less than 10 years of age and may result in a much weaker immune response than in children 10 years of age and older. The adjuvanted vaccine has been studied in this age group and has been shown to provide good protection.

### **Who should not have the H1N1-2009 vaccine?**

The following persons should **not** get the H1N1 -2009 influenza vaccine:

- Infants under six months of age (the current vaccines are not recommended for this age group).
- Anyone with a serious allergy (anaphylaxis) to eggs or egg products. A serious allergic reaction usually means that the person develops hives, swelling of the mouth and throat or has trouble breathing, a sudden drop in blood pressure, or shock after eating eggs or egg products.
- Anyone who has a severe allergy to any component of the vaccine. Your health care provider can tell you which components are in the specific vaccine. Some vaccines contain small quantities of antibiotics or preservatives.
- Anyone who had a serious allergic reaction to a previous dose of the influenza vaccine.
- Avoiding subsequent influenza vaccination of persons known to have had Guillain Barre Syndrome (GBS) within 8 weeks of a previous influenza vaccination appears prudent at this time.

### **Is there any concern for people who have fish allergies receiving the H1N1-2009 adjuvanted vaccine?**

This matter was extensively reviewed with the vaccine regulating body and the vaccine manufacturer and there are no concerns. Persons with fish allergies **can** receive the adjuvanted vaccine. Squalene is naturally present in the human body. The Shark-derived squalene that is used in the production the adjuvant is highly purified. The purification process involves three successive distillation steps at more than 120 C°. This means that any protein present that would cause an allergic response is eliminated by the purification process.

### **Are there any animal products in any of the H1N1-2009 Vaccines?**

Yes, all three of the vaccines contain sodium deoxycholate. Sodium deoxycholate is derived from cows or sheep.

**Can the seasonal influenza vaccine and the H1N1-2009 vaccine be given at the same time? Can the H1N1 vaccine be given at the same time as other vaccines?**

The H1N1-2009 vaccine may be administered concurrently with seasonal influenza vaccine or other vaccines. If pH1N1 influenza vaccine is administered at the same time as both seasonal influenza and

pneumococcal vaccines, the latter two should be given in the arm opposite that used for the pH1N1 influenza vaccine, due to the higher frequency of local reactions to the adjuvanted pH1N1 vaccine.

**Can I get the H1N1-2009 vaccine if I have already had the seasonal influenza vaccine?**

Yes, you may receive the H1N1-2009 vaccine after the seasonal influenza vaccine. If not given concurrently, there is no minimum interval required between the two influenza vaccines. If you got the H1N1-2009 vaccine first, you may receive the seasonal vaccine after. The seasonal influenza vaccine will protect only against the seasonal influenza virus. To be protected from the H1N1-2009 virus you must be immunized with the H1N1-2009 vaccine.

**Where can I get the H1N1-2009 vaccine?**

Contact your local public health unit for service delivery locations for H1N1-2009 vaccine or with your healthcare provider.

**Will vaccination against the H1N1-2009 virus be mandatory?**

No, vaccination against the H1N1-2009 virus is not mandatory. It is voluntary just like the seasonal influenza vaccination program.

**If I have been diagnosed with the H1N1-2009 virus do I have immunity and will I still need a vaccine?**

When a person is infected with the H1N1 virus, they develop antibodies that provide them with immunity to that particular virus. In the case of H1N1 infection, only persons with laboratory confirmed H1N1 infection should not receive the vaccine. People who may have been informed they likely have infection with H1N1 virus which was not laboratory confirmation should receive the vaccine.

**Should I get vaccinated against H1N1-2009 if I have had flu-like illness since the spring of 2009?**

The symptoms of influenza (flu-like illnesses) are similar to those caused by many other respiratory viruses. Even when influenza viruses are causing large numbers of people to get sick, other viruses are also causing illnesses. Specific lab testing is needed in order to tell if an illness is caused by a specific influenza strain or by some other virus. Since most people with flu-like illnesses will not be tested this season, the majority will not know whether they have been infected with H1N1-2009 flu or a different respiratory virus. Therefore, if you were ill in 2009 you should get vaccinated, if your doctor recommends it. So, most people should be vaccinated with the H1N1-2009 vaccine regardless of whether they had a flu-like illness earlier in the year.

Any immunity from H1N1-2009 influenza infection or vaccination will not provide protection against seasonal influenza. All people who want protection from seasonal flu should still get the seasonal influenza vaccine.

### **Which groups will be recommended to receive the H1N1-2009 vaccine first?**

The federal government has ordered enough H1N1-2009 vaccine for every Canadian that needs and wants to be immunized. The basic approach is to ensure those that need the H1N1-2009 vaccine the most get the vaccine first. Groups chosen to receive H1N1-2009 vaccine in the first sequence (those who would benefit most from immunization and/or those who care for them) include:

- People under 65 with chronic health conditions
- Pregnant women
- Healthy children 6 months up to 5 years of age
- Persons residing in remote and isolated settings or communities
- Health care workers involved in pandemic response or the delivery of essential health care services
- Household contacts and care providers of persons at high risk who cannot be immunized or may not respond to vaccines
- Populations otherwise identified at high risk (including those identified by Provinces and Territories)

Others who would benefit from immunization include:

- Healthy children 5 to 18 years of age
- First responders (police, firefighters)
- Swine and poultry workers
- Healthy adults between 19 and up to 64 years of age (this age group is at increased risk for severe H1N1 disease)

### **If I have received the H1N1-2009 vaccine, can I donate blood?**

Yes. It is recommended that after influenza immunization with the H1N1-2009 vaccine, wait at least 2 days before giving blood. Each vaccine has a recommended time interval between vaccination and donation of blood. Please consult your local blood services for specifics.

### **If I have recently donated blood, can I receive the H1N1-2009 vaccine?**

Yes. Please consult your local blood services for specifics regarding time between the donating of blood, and receiving the H1N1-2009 vaccine.

### **Do those that have been previously vaccinated against the 1976 swine influenza need to get vaccinated against the H1N1-2009 vaccine?**

The 1976 swine flu virus and the H1N1-2009 virus are different enough that it's unlikely a person vaccinated in 1976 will have full protection from the H1N1-2009. People vaccinated in 1976 should still be given the H1N1-2009 vaccine.

## Questions re: Vaccine Format

### **Why has Canada ordered a vaccine with an adjuvant for the general population, rather than one that does not have an adjuvant?**

The WHO has recommended that countries use dose-sparing vaccines whenever possible. By developing an adjuvanted vaccine, we use less of the virus material (antigen), allowing us to immunize more people in a timely manner. The addition of the adjuvant substance helps the body develop good protection (also known as an immune response) against the pandemic H1N1 infection.

### **How many components are in the adjuvanted H1N1-2009 vaccine?**

- o In Canada, the adjuvanted H1N1-2009 influenza vaccine includes two-components consisting of: one multi-dose vial containing the antigen suspension: a monovalent, inactivated, split virion, Influenza A H1N1-2009 influenza virus antigen. The suspension is a colourless light opalescent liquid.
- o A second vial containing the adjuvant emulsion (AS0<sub>3</sub>). The emulsion is a whitish homogenous liquid, resembling milk.

### **What is an adjuvant?**

An adjuvant is a substance added to a vaccine to help boost the immune response and increase protection. Adjuvants make it possible to reduce the amount of antigen per dose or the total number of doses needed to achieve immunity.

### **What type of adjuvant is used in the H1N1-2009 vaccine?**

The adjuvant AS0<sub>3</sub> is a trade name for a squalene-based immunologic substance used in pandemic influenza A H1N1-2009 vaccine and other various vaccine products by GlaxoSmithKline (GSK).

### **What is squalene?**

Squalene is a naturally occurring substance found in plants, animals, and humans. It is manufactured in the liver of every human body and circulates in our bloodstream. Squalene is commercially extracted from fish oil, and in particular shark liver oil. Squalene used in pharmaceutical products and vaccines is purified from this source.

### **What is known about the safety of squalene in vaccines?**

Twenty two million doses of Chiron's influenza vaccine (FLUAD) have been administered safely since 1997. This vaccine contains about 10mg of squalene per dose. No severe adverse events have been associated with the vaccine. Some mild local reactions (redness, swelling, pain) have been observed and disappeared in 24 to 48 hours. Clinical studies on squalene-containing vaccines have been done in infants and neonates without evidence of safety concerns.

As stated in the Product Information Leaflet, shark-derived squalene is highly purified. The purification process involves three successive distillation steps at more than 120 C°. This means that any protein present would have been eliminated in the process. Individuals allergic to fish would be allergic to a protein and not to any oil from the fish. Furthermore, squalene itself is naturally present in the human body.

**Why is ASO3-adjuvant included in GSK's pandemic 2009 H1N1 vaccine?**

Available clinical data have shown that an oil-in-water adjuvanted vaccine can help mount a robust response against possible pandemic viruses such as the H5N1 and H1N1 influenza viruses. For this reason, GSK has chosen an adjuvant formulation because a smaller amount of antigen is needed for each dose of vaccine produced (dose sparing) as its preferred option for its pandemic influenza vaccines. Canada supported the WHO recommendation to use adjuvanted influenza vaccine to protect Canadians.

**Which countries are currently using vaccine with ASO<sub>3</sub> adjuvant?**

GSK's ASO<sub>3</sub> adjuvanted H5N1 pre-pandemic influenza vaccine is approved in all 27 European states, Malaysia and Hong Kong. This vaccine was developed for stockpiling by governments in advance of avian influenza and currently GSK is not aware of clinical use of this vaccine in these regions.

**Will there be a non-adjuvanted vaccine available?**

Yes. GSK is developing an adjuvanted H1N1 vaccine as recommended by the WHO. The Public Health Agency of Canada has ordered a small quantity of unadjuvanted vaccine which will be available in Ontario early in November.

**Does the vaccine contain the preservative, thimerosal?**

Yes. After mixing the contents of the ASO<sub>3</sub> adjuvant emulsion with the virus antigen suspension, each 0.5mL dose of the vaccine contains thimerosal, a mercury derivative (5µg per dose), as preservative. In line with WHO's guidelines, a preservative is necessary in multi-dose vials and thimerosal remains the most effective preservative.

**Will a single dose, thimerosal free format be available?**

No. there will not be a thimerosal free H1N1 -2009 vaccine.

**Is there latex in the stoppers of the vials?**

The stopper is made of butyl rubber, and is latex free.

**Is there anything available for those with severe hypersensitivity to eggs?**

No, there is no H1N1-2009 vaccine currently available for those with a severe hypersensitivity to eggs. Because the vaccine is manufactured in eggs, people with a documented severe hypersensitivity to eggs should not be vaccinated with the H1N1-2009 vaccine. If they developed swelling of the mouth or throat, hives, or trouble breathing after a previous influenza vaccination they should consult with their healthcare provider.

**Is the vaccine inactivated?**

Yes, it is made from "killed" viruses.

**Is the product light sensitive?**

Yes, it is recommended that the H1N1-2009 vaccine be protected from light until ready to administer.

## Questions re: Influenza Antivirals:

### **Are there drugs that can treat pandemic influenza A H1N1-2009 virus?**

Yes. The use of Oseltamivir (Tamiflu) or zanamivir (Relenza) can be used for the treatment and/or prevention of infection with pandemic influenza A H1N1-2009 virus. Influenza antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the influenza by keeping influenza viruses from reproducing in your body. If you get sick, antiviral drugs can make your illness milder, and make you feel better faster. They may also prevent serious influenza complications. During the current pandemic, the priority use for influenza antiviral drugs is to treat severe influenza illness (for example hospitalized patients) and people who are sick who have a condition that places them at high risk for serious influenza-related complications. Influenza antivirals work best when they are given within 48 hours of the onset of symptoms.

### **What are the Public Health Agency of Canada (PHAC)'s recommendations for the use of antivirals?**

PHAC's recommendation is that antivirals be used to treat pandemic H1N1-2009 influenza infection when the illness is moderate to severe and the patient is at a high risk for complications. PHAC is not recommending that antivirals be given for a mild disease or as a preventive basis at this time. The reasons for this are:

We do not have sufficient information to suggest that this influenza virus requires the use of antivirals for everyone with influenza symptoms. Most people who have symptoms of influenza in Canada are recovering well on their own. There is a risk that the virus could become resistant to antivirals if they are used to treat mild illness or to prevent illness. There are limited amounts of antivirals in the provincial stockpile; we want to be sure that the people who need it most are able to get it.

### **What is the difference between an influenza antiviral and a vaccine?**

Antivirals are drugs used for the prevention and early treatment of influenza. If taken shortly after getting sick (within 48 hours), they can reduce influenza symptoms, shorten the length of illness and may reduce serious complications from influenza infection.

Antivirals work by reducing the ability of the virus to reproduce but do not provide immunity against the virus. The H1N1-2009 Flu Virus can be treated with two different antivirals, oseltamivir (Tamiflu) and zanamivir (Relenza).

A vaccine is any preparation intended to produce immunity to a disease by stimulating the production of antibodies. Vaccines are the best way to prevent illness and death from influenza. They stimulate the production of antibodies against the flu virus components included in the vaccine, providing immunity against the virus.

In order to provide the best protection, a vaccine must be tailored to fight off specific strains of influenza.

### **Can I get the vaccine if I am taking the antivirals?**

You should speak with your primary care provider before receiving the H1N1-2009 vaccine while taking antivirals.

### **Could the H1N1-2009 virus become resistant to oseltamivir and zanamivir?**

Yes, resistance can develop to antiviral drugs used for influenza. Therefore Canada and its global partners, including WHO, are monitoring antiviral drug resistance. The H1N1-2009 Flu Virus is already resistant to Amantadine, another type of influenza antiviral. That is why we have to be careful not to overuse these drugs.

**Should I take an antiviral now just in case I catch the new virus?**

No. You should only take an antiviral, such as oseltamivir or zanamivir, if your health care provider advises you to do so. Individuals should not buy medicines to prevent pandemic influenza A H1N1-2009 virus without a prescription, and they should be careful about buying antivirals over the internet.

## Questions re: Pregnant Women

### **Should pregnant women take special precautions to protect themselves, such as avoiding crowds?**

It's important that people continue their daily lives during the pandemic. It is not recommended that pregnant women avoid going to work, or community social events if they are healthy. In other crowded situations that cannot be avoided, all people including pregnant women should take precautions such as frequent hand hygiene, to avoid picking up the virus. Pregnant women might consider carrying hand sanitizer for the same purpose.

### **What type of vaccine (adjuvanted or unadjuvanted) is recommended for pregnant women?**

Pregnant women should receive the unadjuvanted influenza A (H1N1) 2009 vaccine.

### **Does an adjuvanted vaccine pose a risk to pregnant women?**

All evidence suggests that adjuvanted vaccines are just as safe as unadjuvanted vaccines; however there is no safety data for the use of adjuvanted vaccine in pregnant women. The WHO's Strategic Advisory Group of Experts (SAGE) recommended in July that pregnant women should receive non-adjuvanted vaccine where possible, but that an adjuvanted vaccine could be used if necessary in situations when local pandemic influenza activity is increasing.

## Travel Questions:

### Is it safe to travel?

Yes. WHO is not recommending travel restrictions related to the outbreak of the H1N1-2009 virus. Today, global travel is commonplace and large numbers of people move around the world for business and leisure. Limiting travel and imposing travel restrictions would have very little effect on stopping the virus from spreading, but would be highly disruptive to the global community.

The H1N1-2009 virus has already been confirmed in many parts of the world. The global response now focuses on minimizing the impact of the virus through the rapid identification of cases, and providing patients with appropriate medical care, rather than on stopping its spread internationally.

### I am traveling and I have been immunized with H1N1 vaccine, do I need to bring my 2009-2010 Flu History and Vaccination Record ("Flu Pass") with me?

If you are planning on traveling and you have been immunized with H1N1 vaccine it is recommended to carry proof of immunization (your "Flu Pass") with you when you travel. Each client that is immunized with influenza vaccine must be provided with written proof of immunization at the time of immunization. If you do not have this record, and proof of immunization is required for travel, please contact your vaccine provider to obtain your **2009-2010 Flu History and Vaccination Record**.

### I am traveling to the Hajj in 2009. Do I need the H1N1-2009 vaccine?

Yes. It is a recommendation from the Public Health Agency of Canada, and a requirement of the Saudi Arabian government that all travellers to the Hajj provide documentation of **both** seasonal and H1N1-2009 vaccination, at least 2 weeks prior to entering the country. Please note that the dates for the Hajj pilgrimage in 2009 are November 25 – November 30, 2009.

### How can I protect myself from H1N1-2009 when I am travelling?

People who are ill should delay travel plans. Returning travelers who become ill should contact their health care provider.

***For further information on the pandemic influenza A H1N1-2009 vaccine contact your local public health unit or your health care provider.***

## References

**Apanrix™H1N1 AS03-Adjuvanted H1N1 Pandemic Influenza Vaccine – Emulsion for Injection, Product Leaflet, GlaxoSmithKline Inc., Prepared 21 October 2009.**

**Guidance Document on the Use of Inactivated Pandemic Influenza A (H1N1) 2009 Monovalent Vaccine Revised November 13, 2009, Public Health Agency of Canada (PHAC).** Retrieved from <http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/pdf/monovacc-guide-eng.pdf>

**Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) – Suspension for Injection. Product Leaflet, GlaxoSmithKline Inc., Prepared 12 November 2009.**

**Panvax® H1N1 Vaccine – Product Leaflet, CSL Limited, Prepared September 2009.**

**The Ontario Ministry of Health and Long-Term Care**  
<http://www.health.gov.on.ca/en/ccom/flu/>

**The Public Health Agency of Canada**  
[http://www.phac-aspc.gc.ca/alert-alerte/h1n1/faq\\_rg\\_h1n1-eng.php](http://www.phac-aspc.gc.ca/alert-alerte/h1n1/faq_rg_h1n1-eng.php)  
<http://www.phac-aspc.gc.ca/tmp-pmv/2009/hadj-pilgrim090925-eng.php>

**The World Health Organization**  
[http://www.who.int/csr/disease/swineflu/frequently\\_asked\\_questions/swineflu\\_faq\\_antivirals/en/index.html](http://www.who.int/csr/disease/swineflu/frequently_asked_questions/swineflu_faq_antivirals/en/index.html)

**The US Center for Disease Control**  
[http://www.cdc.gov/h1n1flu/vaccination/public/vaccination\\_qa\\_pub.htm](http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm)  
<http://www.cdc.gov/h1n1flu/qa.htm>

**The United States Government**  
<http://www.flu.gov/news/blogs/vaccinevoluntary.html>