

H1N1-2009 Influenza Q & A – With a Focus on Panvax®

1. What H1N1 vaccines are available in Canada?

The vaccines available in Canada to protect against H1N1-2009 influenza are:

- Arepanrix™ (with adjuvant)
- Panvax® (without adjuvant)
- Influenza A (H1N1) 2009 Monovalent Vaccine (without adjuvant)

Pandemic Influenza H1N1-2009 Vaccine Supply	
Vaccine Strain	A/California/7/2009 (H1N1)-like virus
Vaccine Products	<p>Arepanrix™ (with adjuvant), <i>produced by GlaxoSmithKline (GSK).</i> One multi-dose vial containing the antigen suspension and a second vial containing the adjuvant; an oil-in-water emulsion (AS03) (emulsion is a whitish homogenous liquid).</p> <p>Influenza A (H1N1) 2009 Monovalent Vaccine (without adjuvant), <i>produced by GSK.</i></p> <p>Panvax® (without adjuvant), <i>produced by CSL Limited.</i></p> <p>NOTE: These purified, detergent-split, inactivated, monovalent virus containing influenza vaccine products are propagated in eggs.</p>
Thimerosal-Free	Not available through the H1N1-2009 Immunization Program
Single Dose Format	Not available through the H1N1-2009 Immunization Program
Latex-Free	All three products are latex-free
Antibiotic-Use	<p>Arepanrix™ and Influenza A (H1N1) 2009 Monovalent Vaccine are free of antibiotics</p> <p>Panvax® contains trace residual amounts of neomycin and/or polymyxin B sulfate</p>
Formaldehyde Use	<p>Arepanrix™ and Influenza A (H1N1) 2009 Monovalent Vaccine contain trace residual amounts of formaldehyde</p> <p>Panvax® is free of formaldehyde</p>
Egg-proteins	All three products contain trace residual amounts of egg-proteins
Sodium deoxycholate	All three products contain trace residual amounts of sodium deoxycholate
Sucrose	All three products contain trace residual amounts of sucrose
Light Sensitivity	All three products are sensitive to light and must be contained in packaging that provides protection from light.

2. Can the H1N1 vaccines be administered at the same time as other vaccines?

The H1N1-2009 vaccine may be administered concurrently with seasonal influenza vaccine or other vaccines. If H1N1-2009 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 H1N1-2009 influenza vaccine, due to the higher frequency of local reactions to the adjuvanted H1N1-2009 vaccine.

3. Which H1N1 vaccine should be given to 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 concern of pregnant women 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 who are in the second half of pregnancy (e.g. above 20 weeks gestation) can be offered adjuvanted vaccine.

4. Who should get the Panvax® vaccine?

The unadjuvanted Panvax® vaccine should be reserved for pregnant women.

5. Who should not get the Panvax® vaccine?

The following persons should **not** get the Panvax® vaccine:

- Anyone who is not pregnant.
- Pregnant women 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. These pregnant women should consult with their doctor and consider seeing an allergist before receiving the vaccine.
- Pregnant women who have a severe allergy to any component of the vaccine.
- Pregnant women who have had a serious allergic reaction to a previous dose of influenza vaccine.
- It is not known whether the influenza vaccine causes an increased risk of recurrent Guillain-Barré Syndrome (GBS) in persons who previously had GBS. Pregnant women who have previously developed GBS within the first 8 weeks following an influenza immunization should avoid influenza immunization in the future.
- Pregnant women with bleeding disorders or who are taking medication that could affect blood clotting should discuss their medical situation with their health care professional before receiving the vaccine.

6. What are the risks from the Panvax® vaccine?

The Panvax® vaccine, like any medicine, is capable of causing side effects, which can be either mild, or occasionally, severe. The risk of the vaccine causing serious harm is extremely small. Most people who get any type of vaccine have either no side effects or mild side effects such as soreness, redness or swelling at the injection site. Life-threatening allergic reactions are very rare. If there is difficulty breathing, swelling of the tongue or mouth they should seek medical attention immediately.

All data to date indicates that adjuvanted vaccine is as safe as unadjuvanted vaccine.

The risks from the Panvax® vaccine are:

- Anaphylactic hypersensitivity to previous influenza vaccination, or to eggs, thimerosal, neomycin, polymyxin B sulfate, or any other components in the vaccine.
- Immunization should be postponed in people who have febrile illness or acute infection.

7. How many doses of Panvax® vaccine do pregnant women need?

Pregnant women require 1 x 0.5 ml dose of Panvax® vaccine.

8. How is the Panvax® vaccine packaged?

The Panvax® vaccine is available in a multi-dose glass vial.

Multi-dose vials:

- The package size is 10 or 50 vials.
- The Panvax® vaccine vial must be used **within 28 days** once the stopper has been pierced.
- The stopper of the Panvax® vaccine vial must be pierced no more than **18 times** to ensure stopper integrity.
- Aseptic technique must be used to withdraw each dose, using a separate sterile needle and syringe.
- Any pre-drawn syringes containing the Panvax® vaccine must be used within the one vaccination session (up to a maximum time of **4 hours**) and **cannot** be stored for use at a later date.
- At the end of the 24 hour period, any remaining contents within the vials should be disposed in approved biomedical waste containers according to local and/or provincial regulations

Presentation: each multi-dose vial contains 5 ml or 10 ml of vaccine and is closed with a latex-free stopper and sealed with an aluminum crimp seal. The aluminum seal has a plastic tear-away cap attached that is removed to gain access to the vial closure. The cap is present to protect the vial closure and to indicate if the vial has been tampered with. Once removed, the cap cannot be re-affixed to the vial. The sealed units are packed into a cardboard carton.

9. How should the Panvax® vaccine be stored?

The Panvax® vaccine should be:

- Stored between +2°C to +8°C prior to and immediately after each use.
- After initial use of the vial (piercing of the stopper), Panvax® can be stored under appropriate cold chain conditions for a period of 28 days. The date should be clearly indicated on the multi-dose vial immediately upon initial use.
- Protected from light during storage.
- NOT EXPOSED TO FREEZING TEMPERATURES

The shelf life of the Panvax® vaccine is 12 months when stored between +2°C to +8°C. The expiry date is indicated on the container label.

10. When can pregnant women get the Panvax® vaccine?

Unadjuvanted Panvax® vaccine may be administered at any stage of pregnancy.

11. Is there information from the federal government of Canada about the use of Panvax® vaccine?

Yes, on November 5, 2009 an Addendum to the October 21, 2009 Guidance Document on the Use of Pandemic Influenza A (H1N1) 2009 Inactivated Monovalent Vaccine was posted on the Public Health Agency of Canada website at the following link:

<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/pdf/Panvax-Addendum-eng.pdf>

The document is entitled "Use of Panvax® H1N1 Vaccine (CSL Biotherapies Inc.) (Unadjuvanted)"

12. Are there recommendations from the Canadian Immunization Committee (CIC) about Panvax® and Pregnancy?

Yes, the recommendations for pH1N1 Vaccine in Pregnancy documents have been posted on the PHAC website at:

<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/pregvacc-grossvacc-eng.php>

<http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/pregvacc-grossvacc-fra.php>

13. How has Panvax been authorized for use in Canada?

Canada recently purchased an additional 200,000 doses of unadjuvanted Panvax H1N1 vaccine from CSL Limited, Australia, in order that an alternate vaccine option would be available for the vaccination of pregnant women in Canada by public health officials.

The Minister of Health has authorized the sale of this vaccine in Canada under an interim order. The Public Health Agency of Canada (PHAC) started distributing this unadjuvanted vaccine to provinces/territories on Monday, November 2, 2009.

14. How are Panvax® Adverse Events Following Immunization being monitored?

Emergency departments and primary care providers should report an adverse event following immunization with an H1N1 vaccine to their local medical officer of health within 24 hours after the reportable event is recognized. Post marketing surveillance of AEFIs is important for vaccine safety.

To report an adverse event, fill out the AEFI report form included in the H1N1 vaccine immunization package and send to the local public health unit. Alternatively, call the local public health to report the adverse event. A list of public health units can found at

http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.