

**Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)
GlaxoSmithKline (GSK) Product**

Highlights from the Product Information Leaflet & PHAC Guidance Document

Indications: The Public Health Agency of Canada recommends this unadjuvanted GSK H1N1 vaccine for **pregnant women** and **healthy people 10 to 64 years of age**

Composition:

- 15 µg HA-A/California/7/2009(H1N1)v-like strain (A/California/7/2009, NYMC X-179)(H1N1)v)
- Clinically relevant nonmedicinal ingredients: thimerosal (each 0.5 mL dose contains 50 µg Thimerosal USP as a preservative agent), trace amounts of egg proteins, formaldehyde, sodium deoxycholate, and sucrose

The Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) is very similar in composition and mechanism of action as the licensed FLUVIRAL[®] seasonal influenza vaccine. This pandemic vaccine has been authorized based on data obtained with FLUVIRAL[®] and preliminary results and safety data from GSK.

Instructions for Use:

- Vaccine is a translucent to whitish opalescent suspension that may sediment slightly. Do not administer if the contents appear discoloured
- Shake the multidose vial vigorously each time before withdrawing a dose of vaccine
- Each vial contains 10 x 0.5 mL doses
- Mark the date and time of withdrawal of first dose from the vial. Once the vial is punctured, any unused product should be discarded after 28 days.
- Record the lot number in the patient record
- Each vaccine dose withdrawn into a syringe for injection should be allowed to reach room temperature before use
- Administer by IM injection into the deltoid muscle or anterolateral thigh
- Maintain the vial in the fridge between 2° - 8°C in the original packaging in order to protect it from light.

Dosing

Population	Dosage(ml)	Number of doses required
10 years and older	0.5	1
Pregnant women	0.5	1

Administration Considerations

- Contraindicated in patients with a history of a life-threatening anaphylactic reaction to any of the constituents or trace residues of this vaccine.
- Immunization should be postponed in patients with severe febrile illness or acute infection.
- No data is available on the concomitant administration of Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) with other vaccines, including seasonal trivalent influenza vaccines. However, if co-administration is indicated, immunization should be carried out in separate contralateral arms.
- There is no minimum interval required between the two influenza vaccines.

Adverse Reactions

Very common side effects include pain at the injection site, headache, fatigue, redness and/or swelling at the injection site, shivering, sweating, aching muscles, fever and joint pain.

As with any vaccine, serious reactions that may be attributable to the administration of the Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant) need to be reported as an adverse event following immunization (AEFI). These include but are not limited to body rash and/or severe pruritus, shortness of breath, and facial/throat swelling.