



**A/H1N1 Influenza Vaccine (Adjuvanted, Arepanrix™) {A/California/7/2009 (H1N1)v-like virus}
Split Virus, Inactivated** **Supplier: GlaxoSmithKline**

INDICATIONS ①	<p>1. Strongly recommended for:</p> <ul style="list-style-type: none"> • Individuals < 65 years of age with chronic health conditions^② • Pregnant women in the second half of pregnancy (≥ 20 weeks gestation) ^③ • Residents of remote and isolated settings or communities • Children 6 to 59 months of age • Health care Workers • Household contacts and care providers of infants < 6 months of age, and of persons who are immunocompromised <p>2. Recommended for:</p> <ul style="list-style-type: none"> • Children 5 to 18 years of age • First responders (police, firefighters) • Poultry and swine workers • Adults 19 to 64 years of age • Adults ≥65 years of age
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DOSE BY AGE GROUP	Age Group	Dosage	No. of Doses
	6 months - 9 years (inclusive)	0.25 ml IM	2 doses, 21 days apart ^④ except for healthy children aged 3-9 years, who require only 1 dose, for now ^⑤
	≥ 10 years	0.5 ml IM	1 dose

CONTRA-INDICATIONS	<ol style="list-style-type: none"> 1. History of anaphylactic reaction to a previous dose of influenza vaccine, or to any component of Arepanrix™ 2. History of anaphylactic reaction to eggs 3. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a previous dose of influenza vaccine 4. Infants less than 6 months of age 5. Oculorespiratory syndrome (ORS) severe enough to result in hospitalization.
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VACCINE COMPONENTS	3.75 µg HA - A/California/7/2009(H1N1)v-like strain, squalene, alpha-tocopherol, polysorbate 80, sodium dihydrogen phosphate, potassium dihydrogen phosphate potassium chloride, thimerosal ^⑥ , traces of egg protein, formaldehyde, sodium deoxycholate and sucrose.
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ADVERSE EVENTS	<p>Local: pain, redness and swelling, axillary lymph node tenderness</p> <p>Systemic: myalgia, fever, headache, malaise</p> <p>These events occur more frequently than following seasonal influenza vaccines.</p>
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SPECIAL CONSIDERATIONS	<p>SEE OVERLEAF FOR MIXING INSTRUCTIONS</p> <p>Use resulting vaccine within 24 hours of mixing</p> <p>Administer Arepanrix™ at the same time as seasonal influenza vaccine, and in a separate limb. May be given with other vaccines. Because of recommendation to give Arepanrix™ in a separate limb, routine childhood immunization (e.g., MMR at 12 months) may be deferred by the appropriate interval (e.g., 4 weeks if varicella given and MMR deferred).</p>
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- ① The “Guidance on H1N1 Vaccine Sequencing” including the rationale for groups is available at <http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/vacc-eng.php>
- ② Refer to Influenza Vaccines pages, “Adults (including pregnant women) and children with chronic health conditions”, at the following link: www.bccdc.ca, click on Immunization Manual, click on Section VII
- ③ Pregnant women should preferentially receive the unadjuvanted monovalent pH1N1 vaccine
- ④ Use same type of influenza vaccine for both doses of pH1N1 vaccine (i.e., two adjuvanted or two unadjuvanted).
- ⑤ Parents should be informed to check for updates to this recommendation in 3 – 4 weeks on the provincial websites or call their immunization provider to inquire.
- ⑥ Large-scale studies have shown no association between childhood vaccination with thimerosal-containing vaccines and autism-spectrum disorders. There is insufficient evidence related to administration of thimerosal-containing vaccines in pregnancy. Any risk, if at all, is theoretical.

Instructions for Mixing of Antigen and Adjuvant

Arepanrix™ H1N1 consists of two containers: one multidose vial containing the 2.5 ml of **antigen (suspension)** in a 10 cc vial and a second multidose vial containing 2.5 ml of the **adjuvant (emulsion)** in a smaller 3 cc vial. The antigen suspension is a translucent to whitish opalescent suspension that may sediment slightly. The emulsion is a whitish homogeneous liquid.

Prior to administration, the two components should be mixed using the following technique:

- 1) Shake each vial and inspect for any abnormal physical appearance.
- 2) Do not inject air into the adjuvant vial prior to withdrawal of the adjuvant as it will make withdrawal more difficult. Withdraw all of the white adjuvant emulsion from the smaller of the two vials. This volume may exceed 2.5 ml. Withdraw all of it. Use a 20-23 gauge needle and a 5 cc or larger syringe.
- 3) Inject all of the adjuvant into the larger 10 cc vial containing the clear antigen suspension.
- 4) Shake the resulting mixture. It should appear whitish. Inspect for any abnormal physical appearance. If grey specks are present, shake the vial more vigorously to dissolve them. If bits of rubber (from the stopper) are apparent, do not use the vaccine. Call the BC Centre for Disease Control Pharmacy and Vaccine Services for instructions regarding returning the vial. Phone: (604) 707-2582.
- 5) The resulting 5 ml volume corresponds to 10 doses of vaccine.
- 6) Shake the vial prior to withdrawal of each dose.
- 7) Use a 3 cc syringe with a 25 gauge needle for withdrawal of each dose and for administration. A 1 cc syringe may be preferable for 0.25 ml paediatric doses.
- 8) **Mixed vaccine must be used within 24 hours. Write the time date of mixing onto the vial, and also record the outer package lot number onto the vial.** Record that lot number into the patient record.

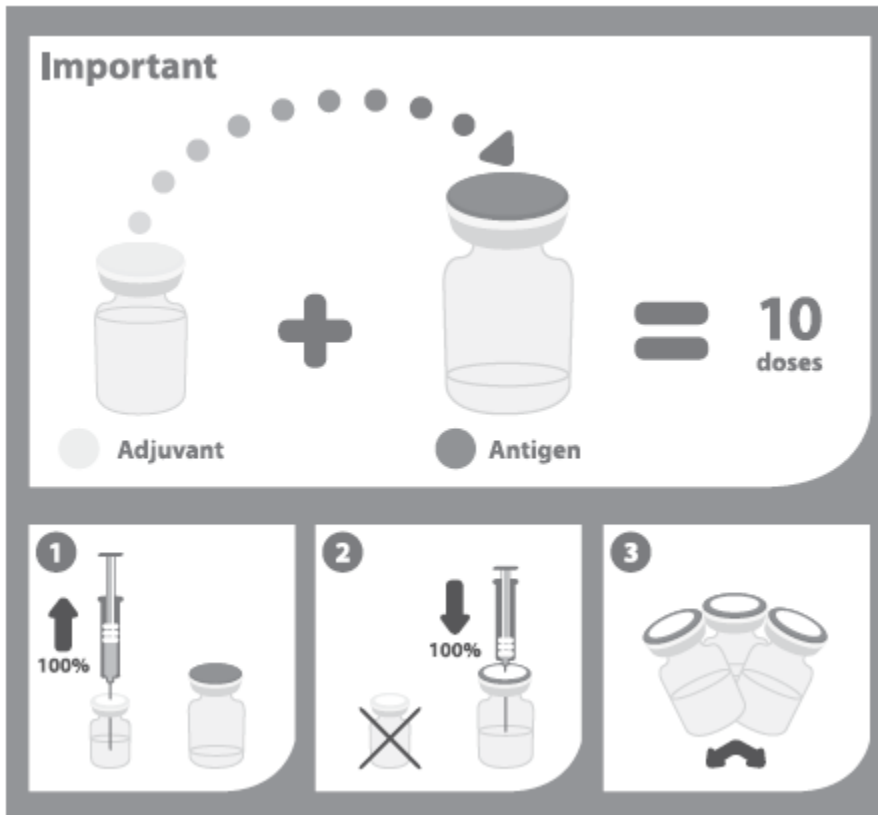


Image courtesy of GlaxoSmithKline

Review Health Professionals Instructional Materials that describe how to mix the vaccine and other recommendations for use at <http://www.immunizebc.ca/ImmForHP/H1N1.htm>