

## AREPANRIX™ H5N1

AS03-Adjuvanted H5N1 Pandemic Influenza Vaccine

GlaxoSmithKline Inc.

**Disclaimer:** this Quick Reference is not intended to replace other product specific vaccine references. The document is intended as a quick reference for frequently referred to information. Please refer to the product monograph and vaccine specific resources for all current and complete information

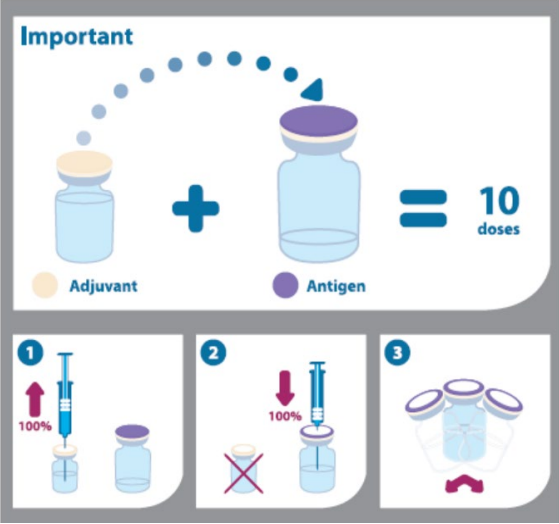
**Product Monograph:** [00078648.PDF](#)

**Manitoba Health's Avian Influenza Webpage:** [Avian Influenza | Health | Province of Manitoba](#)

**National Advisory Committee on Immunization (NACI):** [Rapid response: Preliminary guidance on human vaccination against avian influenza in a non-pandemic context as of December 2024 - Canada.ca](#)

Product/ Presentation	Storage & Handling	Eligibility Criteria	Recommendations for use/ Administration
<p><b>Format:</b> Multidose vials (mixing required) 10 doses/vial Total volume after mixing= 5ml</p> <ul style="list-style-type: none"> <li>2.5 mL of the <u>antigen suspension</u> is contained in a 10 mL vial. 10 vials/package</li> <li>2.5 mL of the <u>adjuvant emulsion</u> is contained in a 3 mL vial for 10 doses. 10 vials/package</li> </ul> <p>Normal appearance of the vials:</p> <ul style="list-style-type: none"> <li>Suspension (antigen): whitish sediments</li> <li>Emulsion (adjuvant): whitish to yellowish homogeneous milky liquid</li> </ul> <p><i>The mixed vaccine is a whitish to yellowish homogeneous milky liquid emulsion.</i></p> <ol style="list-style-type: none"> <li>Allow the adjuvant and antigen vials to reach room temperature (min 15 minutes) prior to mixing.</li> <li>Withdraw the contents of the adjuvant (keep vial upside down to withdraw the full content)</li> </ol>	<p><b>Storage:</b> 2° to 8°C <b>Do not freeze</b> <i>Discard product if exposed to freezing</i></p> <p>Protect from light</p> <p>After mixing, the vaccine should be used within 24 hours:</p> <ul style="list-style-type: none"> <li>The mixed vaccine can either be stored in a refrigerator (2°C - 8°C) or at room temperature (up to 30°C).</li> <li>If the mixed vaccine is stored in a refrigerator, it should be allowed to reach room temperature (min of 15 minutes) before each withdrawal.</li> </ul> <p><i>The vial should be thoroughly mixed by inversion prior to each</i></p>	<ul style="list-style-type: none"> <li>People routinely involved in poultry and/or livestock culling and related operations (e.g. cleaning, disinfection) in the context of suspected/confirmed avian influenza A (H5N1).</li> <li>Personnel working with live avian influenza A (H5N1) virus (culture, isolation, manipulation) in laboratory settings.</li> <li>People who are routinely involved in the response to sick or dead birds or mammals with suspected or confirmed avian influenza A (H5N1) infections, or their environments, including those performing necropsies (e.g. conservation and wildlife</li> </ul>	<p><b>Regimen: 2 doses</b></p> <p><b>Dose:</b> 0.5 mL (adults &gt;18) withdrawn into a 1 mL syringe for injection</p> <p><b>Route:</b> Intramuscular (IM) Deltoid</p> <p><b>Recommended Needle Gauge and Length:</b> 23-25G 1" - 1 ½"</p> <p><b>Interval:</b> Minimum interval between the first and second dose is 3 weeks for maximum efficacy.</p> <p>To minimize interference with seasonal influenza immunization, the avian influenza vaccine series should be completed at least six weeks prior to the fall campaign.</p>

## H5N1 Avian Influenza Vaccine Quick Reference Guide for Immunizers

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<p>using a 5 mL with 23-G needle (if unavailable, use a 21-G needle) and add it to the antigen.</p> <p>3) After the addition of the adjuvant to the antigen, mix the vaccine thoroughly by inversion.</p> 	<p><i>administration and inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed (including rubber particles from the stopper), do not administer.</i></p>	<p>staff, veterinarians or veterinary technicians)</p>	<p><i>There are no data on co-administration of AREPANRIX™ H5N1 with other vaccines. Therefore, coadministration is not recommended. However, if administration of AREPANRIX™ H5N1 with another vaccine is deemed necessary following benefit/risk assessment, immunization should be carried out on separate limbs. In such case, it should be noted that the adverse reactions may be intensified.</i></p>
<p><b>Medicinal ingredients:</b> H5N1 influenza antigen from A/American wigeon/South Carolina/22-000345- 001/2021 (H5N1) strain and AS03 adjuvant. The AS03 adjuvant in AREPANRIX™ H5N1 vaccine enhances the vaccine-induced immune response and contains naturally occurring molecules (squalene and vitamin E) plus an emulsifier (polysorbate 80).</p> <p><b>Non-medicinal ingredients:</b> Disodium hydrogen phosphate, Potassium chloride, Potassium dihydrogen phosphate, Sodium chloride, Thimerosal. Trace amounts of egg proteins, formaldehyde, sodium deoxycholate and sucrose.</p> <p><b>Arepanrix™ H5N1 is contraindicated in those with a history of an anaphylactic reaction to any of the constituents or trace residues of this vaccine, including egg protein</b></p> <p><b>Pregnancy and lactation:</b> No data have been generated in pregnant or breastfeeding individuals with AREPANRIX™ H5N1 and with the AS03 adjuvant system contained in the vaccine. Healthcare providers need to assess the benefits and potential risks of administering the vaccine to pregnant women.</p>			

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