Avian Influenza Vaccine

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.150**	
Created and approved by	Provincial Immunization Program Standards and Quality		
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	Arepanrix H5N1 (A/American wigeon clade 2.3.4.4b)
Manufacturer	GlaxoSmithKline Inc.
Classification	Non-live, inactivated

Indications for Provincially Funded Vaccine	**The following occupational groups are eligible for Arepanrix:**
	• Individuals who handle avian influenza A(H5N1) virus in laboratory settings:
	  ○ Laboratory workers who manipulate, handle, or culture live avian influenza A(H5N1) virus in research laboratory settings including workers from:
	  ▪ University of Alberta Research Team
	  ○ Personnel working in animal diagnostic laboratories including workers from:
	  ▪ University of Calgary Diagnostic Services Unit
	  ▪ Alberta Agriculture and Forestry (AGI) Laboratory
	  ▪ Canadian Food Inspection Agency (CFIA)
	• Individuals with ongoing exposure to birds, poultry, dairy cattle, their carcasses or their environments:
	  ○ Workers who contribute on multiple farms to the management of infected animal cases, for example those exposed to bird culling including but not limited to workers from:
	  ▪ Canadian Food Inspection Agency (CFIA)
	  ○ Wildlife officers, wildlife researchers and wildlife rehabilitators with ongoing exposure to sick and dead birds.
	  ○ Veterinarians, veterinary technicians and other individuals routinely involved in the response to suspected/confirmed avian influenza, including performing necropsies. This includes but is not limited to workers from:
	  ▪ University of Calgary Diagnostic Services Unit
	  ▪ Alberta Agriculture and Forestry (AGI) Laboratory
	Note:
	Clinical laboratory workers, such as those at Alberta Precision Laboratories and Dynalife, are not eligible.

Serology	N/A
Schedule	Individuals 6 months of age and older • Dose 1: day 0 • Dose 2: at least 3 weeks (21 days) after dose 1
Preferred Use	N/A
Dose	Children 6 months to under 18 years of age • 0.25mL

	Arepanrix H5N1 (A/American wigeon clade 2.3.4.4b)
	Adults 18 years of age and older • 0.5 mL
Route	IM
Contraindications/ Precautions	Contraindications: • Known severe hypersensitivity to any component of the vaccine with the exception of egg allergies. Precautions • Immunization should be postponed in patients with severe febrile illness or acute infection, unless the benefits outweigh the potential risks of administering the vaccine to those patients. • Multiple research studies have demonstrated that egg-allergic persons can receive influenza vaccines. All egg-allergic individuals may be immunized with influenza vaccines grown in eggs or chick cell cultures. • If Guillain-Barré Syndrome has occurred in an individual within 6 weeks of receipt of prior influenza vaccine, the decision to give Arepanrix should be based on careful consideration of the potential benefits and risks. Consultation with MOH/designated recommended.
Possible Reactions	**Common:** • Pain, redness, swelling at the injection site • Fever, chills, headache • Fatigue • Joint pain, myalgia • Sweating • Nausea, diarrhea • Irritability in children 6 months to less than 6 years of age • Fatigue in children 6 months to less than 6 years of age • Loss of appetite in children less than 6 years of age **Uncommon:** • Lymphadenopathy • Insomnia • Dizziness, vertigo, paresthesia, malaise • Abdominal pain, vomiting, dyspepsia, stomach discomfort • Pruritus, rash • Musculoskeletal discomfort, chest pain **Rare:** • Anaphylaxis • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	• Consult the MOH/ designate. There is no available data on the use of Arepanrix H5N1 during pregnancy. • There is post market surveillance data on the use of Arepanrix H1N1 and with the AS03 adjuvant during pregnancy. • A GSK-supported safety review of Arepanrix H1N1 and Pandemrix H1N1 vaccines, based on non-clinical, clinical, and post-licensure data, noted that they were generally well tolerated with an acceptable safety profile in special populations including pregnancy.

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	• MOH/Designate will make an individual recommendation based on risk of disease versus benefit of vaccine. **Note**: Data from immunizations with seasonal influenza vaccines in pregnant individuals do not indicate adverse fetal and maternal outcomes were attributable to the vaccine.
Lactation	• May use for people who are lactating and feeding milk to infants or children. • While there are no available data on the use of Arepanrix H5N1 in breastfeeding individuals, use of other influenza vaccines has a strong safety profile in this population.

Composition	Each 0.5 mL dose of vaccine contains:
	• **Active Ingredients**:
	  ○ 3.75 micrograms of A/American wigeon/South Carolina/22-000345-001/2021 (H5N1)
	  ○ Adjuvant containsAS03 composed of squalene, DL-α-tocopherol and polysorbate 80
	• **Non-medicinal Ingredients:**
	  ○ Disodium hydrogen phosphate
	  ○ Potassium chloride
	  ○ Potassium dihydrogen phosphate
	  ○ Sodium chloride
	  ○ Thimerosal
	  ○ Water for injection
	  ○ Trace amounts of egg proteins including ovalbumin (≤0.083 µg per dose), formaldehyde, sodium deoxycholate and sucrose.

Blood/Blood Products	Does not contain any human blood/blood products.
Bovine/Porcine Products	**Bovine Products:** • Bovine derived materials are used as raw material during the routine manufacturing process. **Porcine Products:** • Does not contain porcine products.
Latex	Does not contain latex in the vaccine or packaging.
Interchangeability	N/A
Administration with Other Products	• Wait for a period of at least 6 weeks between administration of Arepanrix and another live or inactivated vaccine unless Arepanrix or another vaccine is needed urgently. ○ Data on co-administration of Arepanrix and other vaccines is not available, • This recommendation is precautionary to prevent erroneous attribution of an adverse event following immunization (AEFI) to one particular vaccine or the other.

Preparation	• Before mixing the two components, the emulsion (adjuvant) and suspension (antigen) should reach room temperature, allow a minimum of 15 minutes.
	  ○ White sediment may be observed in the suspension vial.
	• Invert each vial to mix and then inspect visually for foreign particulate and /or abnormal appearance.
	  ○ Do not administer if anything is seen.
	• Withdraw the entire contents of the adjuvant using a 5 mL syringe and a 23- or 21-gauge needle. Keep the adjuvant vial in an upside-down position to assist the withdrawal of the fill content.
	• The reconstituted vaccine is a whitish to yellowish homogenous milky liquid emulsion.
	  ○ Do not administer if it appears any other way.
	• Use reconstituted vaccine within 24 hours.

	Arepanrix H5N1 (A/American wigeon clade 2.3.4.4b)
	• Store reconstituted vaccine in the fridge between +2°C to +8°C, or at room temperature (up to +30°C). ○ Allow to reach room temperature (a minimum of 15 minutes) before withdrawing and administering, if stored in the fridge
Appearance	H5N1 Antigen: • Sterile, translucent to whitish opalescent suspension that may sediment slightly AS03 Adjuvant: • Sterile, homogenized, whitish to yellow homogenous milky emulsion
Storage	• Store at +2°C to +8°C • Do not freeze.
Vaccine Code	H5N1-AD
Antigen Code	FLU
Licensed for	Active immunization of adults and children from 6 months of age against influenza caused by the H5N1 subtype virus in non-pandemic context. **Note:** Arepanrix H5N1 (A/American wigeon clade 2.3.4.4b) was approved as a strain change to Arepanrix H5N1 (A/Indonesia) by Health Canada under the provisions of the New Drug Submission regulations and standard practice for strain changes to seasonal influenza vaccines.
Program Notes	13 February 2013: Health Canada authorized use of Arepanrix H5N1 (A/Indonesia clade 2.1.3.2) in Canada as a pandemic vaccine. 18 February 2025: Marketing authorization of Arepanrix H5N1 (A/American wigeon clade2.3.4.4b) update as a strain change to Arepanrix H5N1 (A/Indonesia) for use in a non-pandemic context. 5 August 2025: Implemented in Alberta.
Related Resources	Avian Influenza Information Sheet.

References

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