Avian Influenza Vaccine (Inactivated Split Virion, Adjuvanted)
AREPANRIX™ H5N1 Supplier: GlaxoSmithKline Inc.

INDICATIONS:

- Lab workers who routinely handle samples that are likely or known to contain live avian influenza virus or culture avian influenza virus.
- Veterinary staff performing necropsies on potentially infected animals.
- People working in diagnostic laboratories in contact with a large volume of potentially infected carcasses.
- People who repeatedly contribute to the management of infected animals including animal destruction, disposal, or building cleaning and disinfection.
- People working in close contact with wild birds or in/around waterfowl habitats (e.g., wildlife/ animal control officers, wildlife rehabilitation workers, wildlife researchers, hunters and trappers, people working on environmental impact assessment and surveys, people and contractors working on waterborne pathogens, etc.).

The vaccine is not approved for use in those less than 6 months of age.

DOSES AND SCHEDULE:[A]

Children and adolescents 6 months-17 years of age (inclusive): 2 doses given as 0.25 mL **IM**, at least 3 weeks apart.[B]

Adults 18 years of age and older: 2 doses given as 0.5 mL **IM**, at least 3 weeks apart.[B]

ADMINISTRATION:

- **Product needs to be reconstituted.**
- The vaccine consists of two multi-dose vials, a 10 mL vial containing 2.5 mL of antigen (translucent to whitish opalescent suspension that may sediment slightly) and a 3 mL vial containing 2.5 mL of adjuvant (whitish to yellowish homogenous milky liquid).
- Prior to mixing, allow the vials to come to room temperature (allow a minimum of 15 minutes).
- Each vial should be mixed by inversion prior to adding the adjuvant to the antigen. Visually inspect each vial for any foreign particulate material and/or abnormal physical appearance. If either is observed do not mix the vaccine and do not administer.
- Withdraw the entire contents of the vial containing the adjuvant using a 5 mL syringe and adding it to the vial containing the antigen. It is recommended that a 23 gauge needle be used but if not available, a 21 gauge needle may be used.
- After the addition of the adjuvant to the antigen, the vaccine should be mixed thoroughly by inversion. The mixed vaccine is a whitish to yellowish homogenous milky liquid emulsion. Inspect the vial for any foreign particulate matter and/or abnormal physical appearance. If any is observed do not administer the vaccine. The vial should be thoroughly mixed by inversion prior to each administration.
- After mixing, the vaccine must be used within 24 hours.The vaccine may be stored refrigerated (at +2°C to +8°C) or at room temperature (up to +30°C). If the vaccine is stored refrigerated, it should be allowed to reach room temperature (allow a minimum of 15

[A] For information regarding timing of AREPANRIX™ H5N1 and other vaccines, see SPECIAL CONSIDERATIONS.

[B] Based on expert opinion, an 8 week interval between doses may provide better protection.

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ADMINISTRATION (continued):

minutes) before administering. Pre-drawing is not recommended as there is no data on reconstituted H5N1 vaccine stability in a syringe.

BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of AREPANRIX™ H5N1.
2. History of Guillain-Barré syndrome (GBS) within 8 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.

PRODUCT COMPONENTS:

Potential allergens: egg protein, polysorbate 80, thimerosal (5 µg per 0.5 mL dose).

Other components: disodium hydrogen phosphate, potassium chloride, potassium dihydrogen phosphate, sodium chloride, formaldehyde, sodium deoxycholate, sucrose, squalene, DL-α-tocopherol.

PRECAUTIONS:

Not applicable.

SPECIAL CONSIDERATIONS:

- Egg allergic individuals (including those who have experienced anaphylaxis following egg ingestion) can be immunized with AREPANRIX™ H5N1 in any setting attended by immunization service providers who are following standard vaccine administration practice.
- There should be an interval of at least 6 weeks between the administration of AREPANRIX™ H5N1 and any other vaccine to prevent erroneous attribution of an adverse event following immunization. If AREPANRIX™ H5N1 is administered at the same time or within 6 weeks of another vaccine, neither dose needs to be repeated.

ADVERSE EVENTS:

Local: pain, swelling, redness.
Systemic: myalgia, headache, fatigue, arthralgia, fever, shivering, sweating, nausea, diarrhea. Children 6 months to less than 6 years of age may also experience irritability, drowsiness and loss of appetite.