

Arepanrix™ H1N1: AS03-Adjuvanted H1N1 Pandemic Influenza Vaccine

Highlights from the Product Information Leaflet

Arepanrix™ H1N1 consists of two containers: one multidose vial containing the antigen and a second multidose vial containing the AS03 adjuvant.

Instructions for Use:

- Remove a container of antigen and a container of adjuvant from the fridge and let them sit long enough to reach room temperature. This may decrease discomfort at the injection site and allow the adjuvant and antigen to mix together easier.
- Shake both containers.
- Withdraw the entire contents of the vial containing the adjuvant with a syringe and add it to the vial containing the antigen.
- Shake well. The mixed vaccine is a whitish emulsion.
- Mark the date and time of mixing on the mixed multi-dose vial. The mixed multi-dose vial must be used within 24 hours. Discard product if unused within 24 hours following reconstitution.
- Record the lot number in the patient record. The box that the vaccine has been shipped in has three lot numbers written on the outside in the following order; the Arepanrix™ H1N1 lot number, the antigen lot number, and the adjuvant lot number. It is only the Arepanrix™ H1N1 lot number that needs to be recorded.
- Although it is recommended that the mixed product be maintained in the fridge between 2°- 8°C, it may be kept at room temperature for the 24 hour period.
- The volume of Arepanrix™ H1N1 after mixing is 5 mL. This is enough for 10 0.5mL doses.
- The reconstituted vial should be shaken prior to each dose administration.
- Each vaccine dose withdrawn into a syringe for injection should be allowed to reach room temperature before use.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.

Dosing

| Age | Dosage (ml) | Number of doses required |
|----------------------|-------------|--------------------------|
| 6 months to 9 years* | 0.25 | 2 |
| 10 years and older** | 0.5 | 1 |
| Pregnant women*** | 0.5 | 1 |

*Adjuvanted vaccine is recommended due to enhanced immunogenicity. Interval between doses is a minimum of 21 days.

**Adjuvanted vaccine

***Unadjuvanted vaccine is the preferred option for pregnant women. If unadjuvanted vaccine is not available and if pH1N1 activity is increasing or high, pregnant women in the second half of pregnancy should be offered adjuvanted vaccine.

Administration Considerations

Arepanrix™ H1N1 vaccine is contraindicated if there is a history of a life-threatening anaphylactic reaction to any of the constituents or trace residues of this vaccine including egg or chicken proteins.

Immunization should be postponed in patients with severe febrile illness or acute infection.

Arepanrix™ H1N1 vaccine may be administered concurrently (but in the contralateral arm) with seasonal influenza vaccine and/or other vaccines.

If not administered concurrently, there is no minimum interval required between the two influenza vaccines.

If H1N1-2009 vaccine is administered at the same time as either seasonal influenza and pneumococcal vaccines, the latter two vaccines should be given in the arm opposite that used for the H1N1-2009 vaccine.

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 and joint pain. Common side effects include fever, swollen lymph nodes, and diarrhea.

As with any vaccine, serious reactions that may be attributable to the administration of the Arepanrix™ H1N1 vaccine 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.

AS03-Adjuvant

This adjuvant is an oil-in-water suspension that contains DL- α -tocopherol (Vitamin E), squalene (found in the human body and edible oils such as fish liver oil) and polysorbate 80 (found in other vaccines).

Thimerosal

Each 0.5 mL dose contains 5 μ g Thimerosal USP or 2.5 micrograms organic mercury (Hg) as a preservative agent.