

AREPANRIX™ Reconstitution Recommendations

The Ministry of Health and Long-Term Care (MOHLTC) has evaluated the reconstitution process for mixing the H1N1-2009 vaccine (**Arepanrix™**) and is able to provide the following recommendations:

Supplies Required for Reconstitution:

- Syringe with minimum volume of 5 mLs
- 20 gauge needle head no longer than 1 inch in length
- Sharps container
- Antigen & Adjuvant

Reconstitution Process:

1. Warm the adjuvant to room temperature before reconstitution
2. Assemble 5 mL (or 10mL) volume syringe with 1 inch 20 gauge needle head
3. Ensure a vial of antigen (larger vial) and adjuvant (smaller vial) are on hand and the lot numbers of both vials are compatible for use together.
4. Write the date and **time** on the antigen vial immediately before reconstitution
5. Remove caps from antigen and adjuvant vials
6. Shake vial of adjuvant gently to ensure it is mixed well and there are no particles
7. Uncap syringe for use
8. Ensure vial of adjuvant is vertical with top of vial facing upwards
9. Do not insert more than 0.5 mL of air into the adjuvant prior to withdrawing solution, process also works well without inserting air
10. Insert uncapped 5 mL (or 10mL) syringe with 1 inch 20 gauge needle head attached into vertical vial of adjuvant
11. Keep 5 ml syringe with 1 inch 20 gauge needle head inserted inside vial of adjuvant and invert vial
12. Withdraw adjuvant from vial
13. Transfer adjuvant into vial of antigen using 5 mL (or 10mL) syringe with 1 inch 20 gauge needle
14. Remove 5 mL (or 10mL) syringe with 1 inch 20 gauge needle from newly reconstituted vial of Arepanrix™ and discard in sharps container
15. Shake reconstituted vial of vaccine gently to ensure it is mixed thoroughly (colour in vial should be uniform milky white and no particles should be visible).
16. The vial of reconstituted vaccine (Arepanrix™) is now ready for use.
17. Withdraw each dose from the reconstituted vial using 23- 25gauge needle for human injection.
18. The vial of reconstituted vaccine (Arepanrix™) contains enough vaccine for 10 full 0.5 mL doses with a minimal amount of vaccine left over in the vial that should be discarded in the sharps container.

Points to remember:

- Do not use the syringe and needle used for reconstitution for client injection (20 gauge needle is too large)
- For reconstitution use a 5 mL (or 10 mL) syringe with a 20 gauge needle
- For client injection use a 3 mL syringe with a 23-25 gauge needle
- Shake reconstituted vial of vaccine gently prior to each dose withdrawal
- Ensure that proper technique is practiced to prevent needle-stick injuries and vaccine contamination.

AREPANRIX™ Stability

GlaxoSmithKine Canada (GSK) recommends that the vaccine be warmed to room temperature prior to reconstitution. *The rationale for this process is because it provides for easier withdrawal, easier mixing and less pain on injection.* There is no suggested time for the products to reach room temperature as this will depend on the environment.

The preliminary stability information indicates stability of H1N1 vaccine for 24 hours at room temperature (30°C). This refers to the Time out of Refrigeration (TOR) for these lots specifically after mixing. It is recommended that reconstituted vaccine should be stored between 2°C and 8°C.

The Arepanrix™ vaccine is recommended be stored and maintained between 2°C and 8°C, whether it is reconstituted or not, however the products may be kept at room temperature during this period if required after reconstitution. The Arepanrix™ vaccine products do not *need* to be brought up to room temperature prior to reconstitution.

The terminology “if required” in reference to Arepanrix™ vaccine means that if needed the reconstituted Arepanrix™ vaccine can be left at room temperature and will remain stable as long as it is used within 24 hours. This supports the ability to withdraw doses from the vial without having to refrigerate the vaccine after withdrawing each dose.

If the Arepanrix™ products are kept at room temperature and then put back into the fridge at the recommended storage temperature of 2°C and 8°C this does not mean that the vaccine needs to be red dot as exposed because this not considered a cold chain exposure because it is being done within the recommendations provided by the manufacturer. Similarly this does not mean that the time it was at room temperature should be deducted from any remaining temperature such as the 24 hours indicated that is the length of time allotted because the vaccine is being used within the 24 hours time frame recommended by the manufacturer.