

Durham Region Health Department FAX about...

For Health Care Professionals

Product Safety Update: Opening Ampoules for MMR(V) Diluent

GSK is distributing a new diluent ampoule to reconstitute Priorix, Priorix Tetra and Varilrix vaccines. The diluent uses an Open Point Cut (OPC) system. Please refer to the instructions below on how to properly open the ampoule to prevent shattering or wastage.

- The ampoule has 2 red rings and a blue dot on the bulb head. DO NOT open the ampoule from the red rings. The blue dot is a visual mark to indicate the correct location of the thumb placement on the bulb head.
- The OPC ampoule can only be broken in one direction.

2 red rings - colour coding for unique packaging identification, do not open the ampoule here Ampoule bulb head Blue dot - visual mark to indicate the correct location of your thumb placement on the bulb head (step 3 The OPC ampoule breaks open at the neck as normal for glass Body of the ampoule ampoules. However, the OPC ampoule can only be broken in one direction

Opening the Ampoule:

- 1. Ensure there is no liquid at the head (Bulb) of the ampoule by gently flicking the bulb head until the liquid goes into the body of ampoule.
- 2. Hold the ampoule with your non-dominant hand. Ensure the blue dot is facing you.
- 3. With your **dominant hand**, place your **thumb on the blue dot** and hold the bulb head.
- 4. Position the ampoule to tilt at a 45° angle.
- 5. Hold the ampoule steady. Apply force on the thumb placed on the bulb head and **push down** on the blue dot and away from you, exerting leverage on the ampoule neck while resisting with the index finger on the body of the ampoule (pressure point). Keep the force constant for a clean opening.
 - Do not open the ampoule when your thumb is not pressing down on the blue dot.
 - Do not open the ampoule by rotating the bulb head.
 - Do not open the ampoule at the position of the 2 rings.
- 6. The ampoule will crack at the neck and the upper part will detach.
- 7. Extract the liquid to reconstitute the vaccine.

If the ampoule (body or bulb head) breaks into pieces, please discard and use a new ampoule. For further questions or concerns, please contact GSK at 1-800-387-7474 or email cacsu@gsk.com.

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