

Stamaril multi-dose (10 doses) – instructions for use

Nature and content of container

Powder (10 doses) in vial (type I glass), with a stopper (bromobutyl) + solvent in a plastic ampoule to reconstitute 10 doses.

Vaccine in vials and solvent in plastic ampoules are in two separate boxes

- 10 vials of 10 doses (in total 100 doses in one box)
- 10 plastic ampoules for reconstitution of the 10 vials of vaccine

Special precautions for reconstitution

Reconstitution of Stamaril multi-dose must be carried out using only the specific solvent supplied with the product.

Withdraw the totality of the solvent with an appropriate needle and syringe. First reconstitute the freeze dried vaccine in its container with a small quantity of solvent. Shake the vial and after dissolution, add the remaining solvent.

For each vaccination withdraw 0.5 mL of the reconstituted vaccine with an appropriate graduated syringe.

A new syringe and needle must be used for each patient.

After reconstitution, STAMARIL is a beige to pinked beige suspension ready for injection. The reconstituted product must be used within 6 hours, and kept at 2°C to 8°C.

Contact of the stopper or plastic ampoule with disinfectant is to be avoided since they may inactivate the virus.

Any unused product or waste material should be disposed of, preferably by heat inactivation or incineration, in accordance with local requirements.

Storage

The vaccine must be stored in a refrigerator (2°C; 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

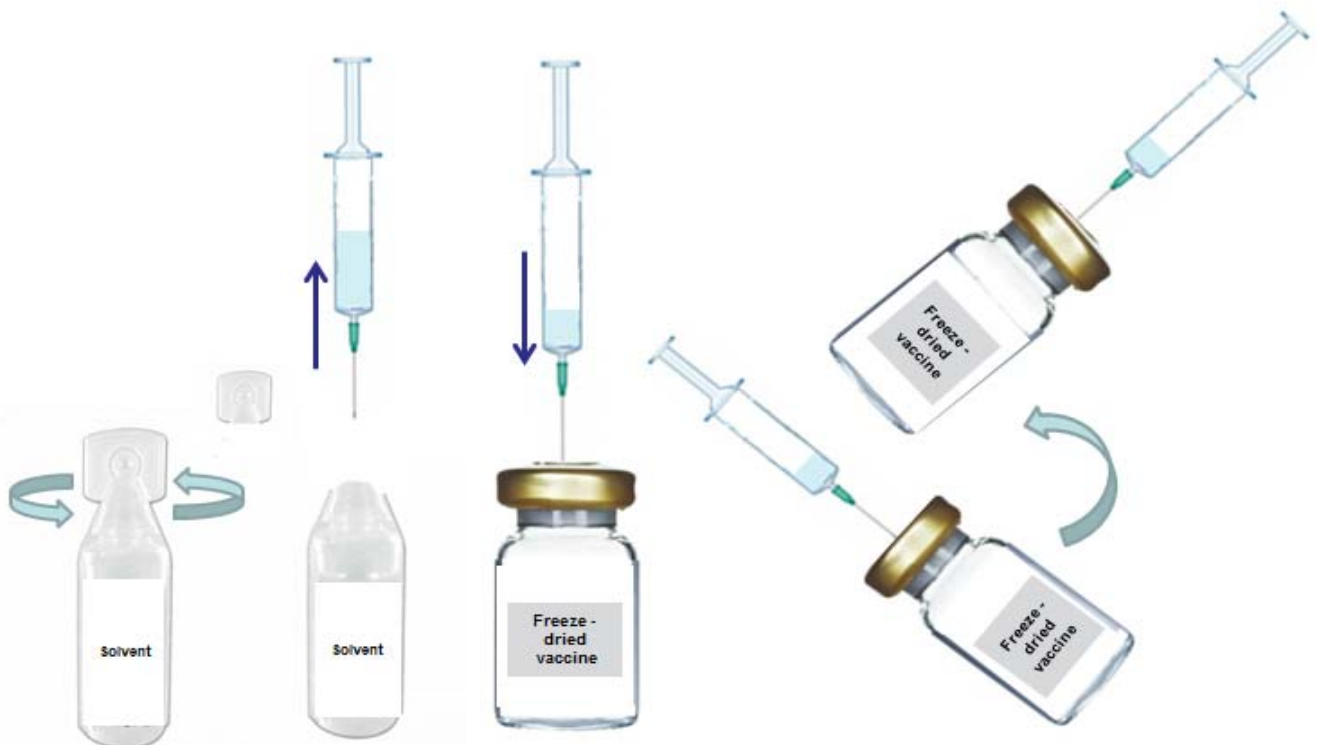
The solvent can be stored at ambient temperature (20°C; 25 °C). Do not freeze.

Wastage prevention

As the reconstituted product must be used within 6 hours, it is recommended that sufficient subjects are invited to the Yellow Fever immunization sessions in order to minimize the number of unused doses.

The optimal condition is to plan a group of 10 subjects for each vial to be reconstituted.

Reconstitution of a multi-dose vaccine - USER GUIDE



Withdraw the totality of the solvent

First reconstitute the freeze-dried vaccine with a small quantity of solvent

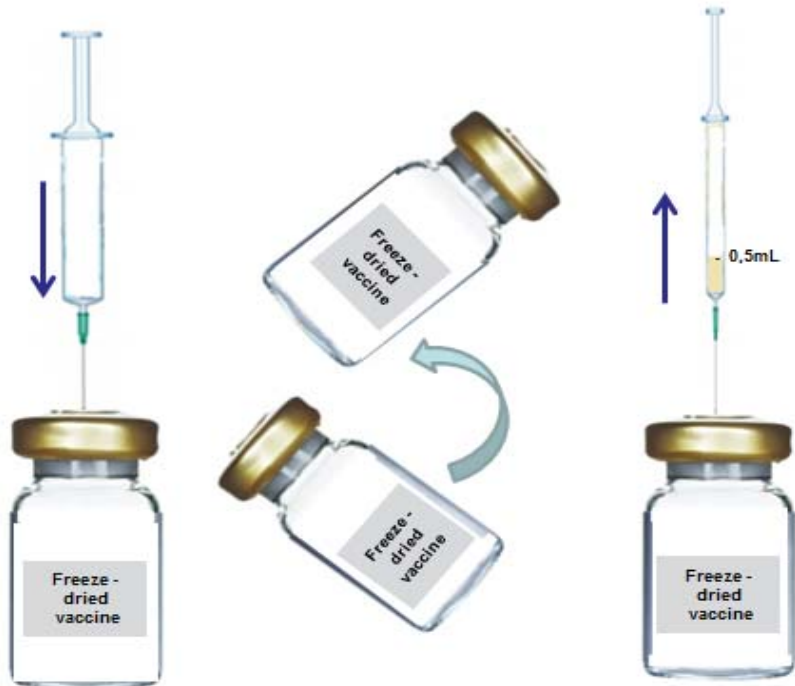
Shake the vial

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After dissolution, add the remaining solvent

Shake the vial

Withdraw 0,5mL of reconstituted vaccine with an appropriate syringe and needle

Preferably change the needle for the injection. Then, inject 0,5 mL to the subject

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