

PACKAGE INSERT – Verorab – Powder for injection vial with diluent pre-filled syringe with attached needle

NAME OF THE MEDICINE

Inactivated Rabies Virus

DOSAGE FORM

Powder and solvent for suspension for injection.

METHOD OF PREPARATION

Preparation:

1. Remove the seal of the vial of lyophilised powder.
2. Inject the solvent into the vial of lyophilised powder.
3. Gently swirl the vial until homogeneous suspension of the powder is obtained. The reconstituted vaccine should be limpid, homogeneous, and free from particles.
4. Remove and discard the syringe that was used for vaccine reconstitution and use a new syringe with a new needle to withdraw the reconstituted vaccine.
5. Replace the needle used to withdraw the reconstituted vaccine by a new needle for intramuscular or intradermal injection.
6. The length of the needle used for vaccine administration should be adapted to the patient and to the route of administration.

Compatibility:

This vaccine must not be mixed with other medicinal products.

IN-USE STORAGE CONDITIONS

If Verorab is used via intramuscular route, once reconstituted, the product must be used immediately.

If Verorab is used via intradermal route, vaccine may be used up to 6 hours after reconstitution provided it is maintained at no more than 25°C and protected from light. After reconstitution, using aseptic technique, a dose of vaccine should be withdrawn from a vial. The product is for single use only and must not be reused. Discard any remaining unused contents. After use, any remaining vaccine and container must be disposed of safely, preferably by heat inactivation or incineration, according to locally agreed procedure.

SPONSOR

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