

## VERORAB

Purified inactivated rabies vaccine, prepared on VERO cells.

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### DESCRIPTION

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VERORAB is a sterile powder and diluent for suspension for injection.

- Freeze-dried Powder

After reconstitution, 1 dose (0.5 mL) contains:

Rabies virus\*, Wistar rabies PM/WI 38 1503-3M strain (inactivated)  $\geq 2.5$  IU\*\*

\* produced in VERO cells

\*\* quantity measured according to the international standard and the NIH test

Maltose	52.5 mg
Human serum albumin	2.5 mg
BME medium†	qs
Water for injection	qs

† BME: Basal Medium Eagle: mixture of mineral salts, vitamins and amino-acids including L-Phenylalanine.

- Diluent - 0.4% sodium chloride solution

Sodium chloride	2mg
Water for injection	qs 0.5mL

VERORAB contains bovine serum albumin (not more than 50 nanogram per dose). The vaccine may contain undetectable traces of betapropiolactone, neomycin, streptomycin and polymixin B which are used during vaccine production.

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### PHARMACOLOGY

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#### Rabies Vaccine

Inactivated vaccine used to prevent rabies in subjects at risk from infection and as a treatment following confirmed or possible infection with rabies virus.

Pre-exposure: Serum antibody level  $\geq 0.5$  IU/mL, considered as protective by the WHO, is achieved after the injection of 3 doses at D0, D7 and D28 (or D21). This immunity must be maintained by a first booster dose 1 year later with subsequent boosters every 5 years.

Post-exposure: Serum antibody level  $\geq 0.5$  IU/mL, considered as protective by the WHO, is achieved after the third injection by D14.

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### INDICATIONS

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VERORAB is indicated for the prevention of rabies prior to exposure and following proven or suspected exposure.

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## CONTRAINDICATIONS

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### Pre-exposure

- The standard contraindications of any vaccination: in the event of fever, acute disease or progressive chronic disease, it is preferable to postpone vaccination.
- Known systemic hypersensitivity reaction to any of the vaccine components including neomycin, streptomycin and polymixin B as described under the section Description.

In all cases, the risk/benefit ratio should be assessed.

### Post exposure

- There are no contraindications to rabies vaccination post exposure.

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## PRECAUTIONS

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Do not inject via the intravascular route: ensure that the needle does not penetrate a blood vessel.

Immunoglobulin and rabies vaccine should not be combined in the same syringe or injected at the same site.

A serological test (assay of neutralising antibodies using the Rapid Fluorescent Focus Inhibition (RFFIT) Test) should be performed every 6 months in subjects with continuous exposure and it may be performed every 2 or 3 years after the boosters at 1 and 5 years in subjects with intermittent exposure, depending on an assessment of exposure risk.

In the case of immunodeficient subjects, a serological test of their antibody level should be performed 2 to 4 weeks after vaccination.

If the antibody level is under that considered to be protective, i.e. 0.5 IU/mL (RFFIT), a booster injection or, in immunodeficient subjects, an additional injection, is justified.

### ***Use in pregnancy (Category B2)***

Pre-exposure: Animal reproductive studies have not been conducted with VERORAB. Data on the use of this vaccine in pregnant women are limited. Therefore, the administration of the vaccine during pregnancy is not recommended. VERORAB should be given to pregnant women only if clearly needed, and following an assessment of the risks and benefit.

Post-exposure: Because of the severity of the disease, pregnancy does not constitute a contraindication in the event of post-exposure vaccination.

### ***Use in lactation***

It is not known whether this vaccine is excreted in human milk. Caution must be exercised when VERORAB is administered to a nursing mother.

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## **INTERACTIONS**

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Corticosteroid and immunosuppressive therapy may interfere with the production of antibodies and vaccination may fail; it is therefore preferable to assay neutralising antibodies 2 to 4 weeks after the last vaccine injection.

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## **ADVERSE REACTIONS**

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The following reactions are known to occur with this vaccine:

Local, benign reactions: pain, erythema, oedema, pruritus, and induration at the injection site.

Systemic reactions: moderate fever, shivering, malaise, fatigue, headache, dizziness, arthralgia, myalgia, gastrointestinal disorders (nausea, abdominal pain).

Anaphylactoid reactions, urticaria and rash occur exceptionally.

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## **DOSAGE AND ADMINISTRATION**

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The vaccine should be administered via the intramuscular route only, in the deltoid muscle in adults or in the anterolateral area of the thigh in infants and toddlers.

Do not inject in the gluteal area. Do not administer by the subcutaneous route.

The vaccination schedule should be adjusted according to the circumstances of vaccination and the subject's rabies immune status.

### **Preventative or pre-exposure vaccination**

- Primary vaccination: 3 injections at D0, D7, and D28
- First booster: 1 year later
- Subsequent boosters: every 5 years

The injection scheduled at D28 may be given on D21.

### **Curative or post-exposure vaccination**

#### **First Aid Treatment**

The treatment of wounds is very important and must be done immediately after being bitten. First of all the wound should be washed with plenty of clean water and soap or detergent, followed by the application of 70% alcohol, iodine tincture or a 0.1% solution of quaternary ammonium (on condition that no traces of soap remain, as these two agents neutralize each other).

If necessary, the treatment should be completed by tetanus prophylaxis and antibiotic therapy to prevent superinfection.

Curative vaccination must be carried out under medical supervision.

### Vaccination of non-immunised subjects

Posology is identical for adults and children: it comprises five 0.5mL injections at D0, D3, D7, D14, and D28.

For exposure involving bites or scratches that penetrate the skin, or where mucosa is contaminated with saliva (licking), rabies immunoglobulin should be administered in association with vaccine. Complementary passive immunisation at D0 is necessary using:

- Human rabies immunoglobulin (HRIG) 20 IU/kg body weight
- Equine rabies immunoglobulin (ERIG) 40 IU/kg body weight

If possible, the vaccine should be injected contralaterally to the sites of immunoglobulin administration.

In enzootic rabies areas, the administration of two injections on D0 may be justified, e.g. in the case of lesions that are extremely severe or located near the nervous system, or when the subject is immunodeficient or did not come in for a medical consultation immediately after exposure.

### Vaccination of subjects who are already immunised (complete proven preventative vaccination)

A complete pre-/post-exposure vaccination with cell culture rabies vaccines or a documented rabies antibody level  $\geq 0.5$  IU/mL: 2 injections at D0 and D3

Vaccination more than 5 years previously or incomplete vaccination: 5 injections at D0, D3, D7, D14, and D28 with the administration of immunoglobulin, if necessary.

In practice, if the last booster was administered more than 5 years previously, or if vaccination is incomplete, the subject should not be considered to be completely immunised.

Because VERORAB does not contain any preservative, the reconstituted vaccine should be used immediately.

Product is for single use in one patient on one occasion only. Discard any residue.

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### **OVERDOSAGE**

Not applicable

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### **PRESENTATION**

1 dose of freeze-dried vaccine in vial (glass) with 0.5mL of solution in syringe (glass) with plunger stopper. Box of 1 vial and syringe.

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### **STORAGE**

Store at 2° to 8°C. REFRIGERATE. Do not use after expiry date. Store protected from light.

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**MANUFACTURER**

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**DISTRIBUTOR/SPONSOR NEW ZEALAND**

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**MEDICINE CLASSIFICATION**

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Prescription Medicine

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**FURTHER INFORMATION**

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VERORAB has provisional consent under Section 23 of the Medicines Act 1981 due to the limited efficacy data available. VERORAB is only supplied when Merieux Inactivated Rabies Vaccine (MIRV) is unavailable.

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**DATE OF PREPARATION**

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25 May 2011

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