

Registration No. : 1C 339/47

Importer / Manufacturer: Sanofi Pasteur Ltd., Thailand/Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : VERORAB

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Freeze-dried vaccine..... 1 immunizing dose
such that the protective activity is equal to or greater than 2.5 International Units, before and after heating for one month at + 37°C.

Rabies virus (Wistar rabies PM/WI38-1503-3M strain) obtained from culture on Vero continuous cell lines, inactivated with β -propiolactone.

VERORAB is produced in accordance with W.H.O. Recommendations

3. PHARMACEUTICAL FORM

Freeze-dried vaccine and solution for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Pre-exposure immunization

This vaccination is particularly recommended for:

Professional groups exposed to frequent contamination:

- veterinary surgeons (including students at veterinary colleges),
- technical personnel working with veterinary surgeons,
- laboratory personnel handling material contaminated with rabies virus,
- personnel in abattoirs and knackers yards
- taxidermists,
- gamekeepers, forestry workers and naturalists in enzootic areas.

Infants particularly exposed to the risk of rabies.

Post-exposure immunization

Treatment of subjects bitten by rabid animals or those suspected of being so.

Treatment of contact subjects.

This vaccination is well tolerated. Due to the gravity of rabies, vaccination during pregnancy must be carried out in cases of rabid contamination.

4.2 Posology and method of administration

Route of administration:

Intramuscular injection into the deltoid region in adults or the anterolateral side of the thigh in small children.

Not to be injected into the gluteal region.

In certain cases the intradermal route may be used (see below).

Reconstitute the freeze-dried powder with accompanying diluent.

Reconstituted vaccine is a homogeneous, limpid solution without any particles in suspension.

Any reconstituted vaccine must be used immediately.

The syringe should be destroyed after use.

a) Pre-exposure immunization

Primary-vaccination:

According to the W.H.O. recommendations 3 x 0.5 ml injections by the intramuscular route on days D0, D7, D21 or D28, followed by a booster one year later.

Boosters:

Thereafter, one injection every 5 years or when the titre is found to be less than 0.5 I.U./ml.

b) Post-exposure immunization

Intramuscular schedule:

Non-vaccinated individuals:

Treatment consists of 5 x 0.5 ml injections.

Intramuscular injections to be given on Day 0, D3, D7, D14 and D28 subsequent to contact with an animal confirmed or suspected of being rabid.

In case of severe (W.H.O. category 3) wounds, immunoglobulins should be administered as soon as possible, see Warnings.

Fully vaccinated individuals:

Vaccinated individuals are those who have received full preventive immunization with a cell culture vaccine (≥ 2.5 I.U./dose) and have a vaccination certificate to prove this.

Vaccine schedule:

- vaccination within the previous 5 years: 2 injections on D0, D3

Intradermal schedule

W.H.O. recognise the effectiveness of rabies vaccine when given by the intradermal route (i.d.) for post-exposure immunization. If VERORAB is administered by the intradermal route, the following instructions and warnings must be strictly adhered to.

Dosage and administration:

One i.d. dose comprises 0.1 ml of reconstituted vaccine, i.e. 1/5 of the i.m. dose. To be administered in the forearm or upper arm.

Non-vaccinated individuals:

The TRCS schedule (known as 222011) is recommended:

- two i.d. injections of 0.1 mL at different sites on D0, D3, D7
- one i.d. injection of 0.1 mL at a single site on D28 (or D30) and D90.

Fully vaccinated individuals (see above definition):

- urgent booster injection of 0.1 ml on D0, D3.

4.3 Contraindication

a) Post-exposure immunization

ALL CONTRAINDICATIONS ARE SECONDARY IN CASES OF SUSPECTED RABID CONTAMINATION.

b) Pre-exposure and booster immunization

In case of pregnancy or acute febrile illness, the vaccination should be deferred.

4.4 Special warnings and precautions for use

- To be used with care in cases of true allergy to streptomycin and/or neomycin (traces present in the vaccine).
- In cases of severe bites, it is recommended by the World Health Organisation that a treatment of 20 I.U. per kg of specific human rabies immune globulin (IMOGAM RABIES) or 40 I.U. per kg of purified rabies serum of equine origin, be given on the first day of vaccination (D0). These immunoglobulins provide protective antibodies immediately, and as much as possible should be administered locally at the wound site(s). (Please refer to the immunoglobulin leaflets for additional information on RIG administration)

Wound cleaning:

In accordance with W.H.O. recommendations, prompt local treatment of wounds should always be carried out. All bite wounds and scratches should be thoroughly flushed with water and washed with soap or detergent. This should be followed by application of 70% alcohol, tincture of iodine or a 0.1% solution of quaternary ammonium (provided that no traces of soap remain as these two products neutralize each other). Sutures should be avoided; if they are necessary however, rabies immunoglobulin should always be infiltrated around the wound.

Special precautions for the intradermal route:

It is essential that intradermal administration of VERORAB be carried out only by medical staff trained in this technique in order to ensure that the vaccine is delivered intradermally and not subcutaneously.

For the intradermal route a sterile syringe with fixed needle (insulin type) is preferred.

A sterile needle and syringe must be used to withdraw and administer each dose of vaccine for each patient to avoid cross infection. Correct intradermal injection should result in a raised papule with a "peau d'orange" (orange peel) appearance. If the vaccine has been injected too deeply and a papule is not seen, the needle should be withdrawn and re-inserted nearby.

VERORAB does not contain a preservative, therefore, great care must be taken to avoid contamination of reconstituted vaccine.

Any reconstituted vaccine should be used as soon as possible. It must be stored in a refrigerator at + 2 - + 8°C and used within the day of reconstitution or discarded.

The i.d. route must not be used in the following instances:

- individuals receiving long term corticosteroid or other immunosuppressive therapy or chloroquine,
- immunocompromised individuals,
- individuals, particularly children, with severe wounds, especially to the head and neck or presenting late for consultation.

4.5 Interaction with other medical products and forms of interaction

Corticosteroid and immunosuppressive treatment may lead to vaccination failure. In these cases, a titration of neutralizing antibodies should be performed.

4.6 Pregnancy and lactation

4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

Local minor reactions like redness and slight induration at the injection site. Rare febrile reactions.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltose	q.s. 1 immunizing dose
Human albumin.....	q.s. 1 immunizing dose
Diluent : solution of sodium chloride 0.4%.....	0.5 ml

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

Between + 2°C and + 8°C. Do not freeze.

6.5 Nature and contents of container

1 dose of lyophilized vaccine in vial (glass) with 0.5 ml of solution in syringe (glass)-box of 1 vial and 1 syringe

6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

1C 339/47

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 November 2004

10. DATE OF REVISION OF THE TEXT

Date of approval: 18 November 2004

(The above information is based on the currently approved leaflet)