

Registration No. 1A 257/45

Importer / Manufacturer: GPO-MBP

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICAL PRODUCT**

VERO RABIES VACCINE

### **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/WI 38 – 1503 – 3M strain) obtained from culture on Vero continuous cell lines, inactivated with  $\beta$  – propiolactone.

Maltose.....q.s. 1 immunizing dose

Human albumin.....q.s. 1 immunizing dose

Diluent: 0.4% Sodium chloride solution.....0.5 ml

### **3. PHARMACEUTICAL FORM**

Vaccine: freeze dried powder with diluent for injection.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

**Pre – exposure immunization** This vaccine is particularly recommended for:

Professional group exposed to frequent contamination:

- veterinary surgeons (including student at veterinary colleges),

- technical personnel working with veterinary surgeons,
- laboratory personnel handling material contaminated with rabies virus,
- personnel in abattoirs and knackers yard,
- 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 adult 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

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 WHO recommendations 3x 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 whenever the titre is found to be less than 0.5 IU/ml.

## **b) Post – exposure immunization**

### **Intramuscular schedule:**

Non – vaccinated individuals:

Treatment consists of 5 x 0.5 ml injections.

Intramuscular injection 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 (WHO category 3) wound, immunoglobulins should be administered as soon as possible.

Fully vaccinated individuals:

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

Vaccine schedule:

Vaccination within the previous 5 years: 2 injections on D0, D3.

### **Intradermal schedule:**

WHO recognize the effectiveness of rabies vaccine when given by the intradermal route (i.d.) for post – exposure immunization. If Vero rabies vaccine 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: urgent booster injection of 0.1 ml on D0, D3.

## **4.3 Contraindication**

- a) **Post – exposure immunization** All contra indications are secondary incases of suspected rabid contamination.
- b) **Pre – exposure and booster immunization** in case of pregnancy or acute febrile illness, the vaccination should be differed.

#### **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 WHO that a treatment of 20 IU per kg of specific human rabies immune globulin (IMOGAM RABIES) or 40 IU 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 wound site (s).

Wound cleaning:

In accordance with WHO 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 precaution for the intradermal route:**

It is essential that intradermal administration of vaccine 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 an orange peel appearance. If the vaccine has been injected too deeply and a papule is not seen, the needle should be withdrawn and reinserted nearby. This vaccine 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 °C to +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**

Vaccination during pregnancy must be carried out in cases of rabid contamination.

#### **4.7 Effects on the ability to drive and use machines**

NA

#### **4.8 Undesirable effects**

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

Rare febrile reactions.

#### **4.9 Overdose**

NA

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

NA

#### **5.2 Pharmacokinetic properties**

NA

#### **5.3 Preclinical safety data**

NA

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

1 immunizing dose (0.5 ml) contains:

Maltose q.s. 1 immunizing dose

Human albumin q.s. 1 immunizing dose

### **6.2 Incompatibilities**

NA

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

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

Store between +2 °C and +8 °C. Do not freeze.

### **6.5 Nature and contents of container**

Vials of both vaccine and diluent: Type I borosilicate glass.

### **6.6 Special precautions for disposal and other handling**

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

## **7. MARKETING AUTHORISATION HOLDER**

Government Pharmaceutical Organization – Mériex Biological Products Co., Ltd.

## **8. MARKETING AUTHORISATION NUMBER(S)**

1A 257/45

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

14 August 2002

**10. DATE OF REVISION OF THE TEXT**

April 2011