Summary of Product Characteristics of Rabies Vaccine, Human I.P.

Brand Name: SURE RAB™

Manufactured By:

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Summary of Product Characteristics

(As per Annexure C of Module 1 of Guidance for industry by CDSCO)

1. Name of the Medicinal Product :-

Rabies Vaccine, Human I.P.
Brand Name: SURE RAB™

2. Qualitative and Quantitative Composition :-

Each vial of lyophilized vaccine contains:-
Inactivated Rabies virus……..≥ 2.5 IU
Stabilizer
Polygeline…….. 10.5mg
Sucrose…….. 25mg
Potassium L-glutamate……. 0.9 mg
Di Sodium edetate (EDTA)……. 0.25mg

3. Pharmaceutical Form :-

Rabies Vaccine, Human I.P., Brand Name: SURE RAB™ -It is an inactivated, purified and Lyophilized preparation of Pitman Moore strain of rabies Virus. The virus is produced on Vero cell culture and inactivated by β Propiolactone.

4. Clinical Particulars :-

4.1 Therapeutic Indications:

Active immunization against rabies for pre-exposure immunization and post exposure immunization in category II and III bites.

4.2 Physiology and method of administration :

Reconstitute the lyophilized vaccine, immediately prior to use with entire content of the vaccine diluent provided with the vaccine, gently agitate until lyophilisate is dissolved completely. Use aseptic technique to withdraw the dose. In case of unforeseen delay, keep reconstituted vaccine at 2^{o} to 8^{o}C. Reconstituted vaccine shall not be used after 6-8 hours of reconstitution. Dose for adult and infant/child is same. Current WHO/ National guidelines may be consulted for Rabies Vaccination/ Immunization.

Vaccination Guidelines: Day 0 indicates date of first injection

A. Pre-exposure Immunization :

The vaccine is recommended for high risk professionals e.g. hunters, veterinarians, animal keeper/ handler, butcher, rabies laboratory personnel, army professional, postmen, municipal workers, forest workers, subjects staying or visiting in rabies endemic areas or at a continuous risk of exposure. A serological test is recommended (every 6 months) in subjects at risk of continuous exposure. For subject at frequent risk WHO recommends antibody titer estimation annually. If titers are below protective threshold of 0.5 IU/ml, one booster dose should be administered.

A booster injection should be administered after one year of primary Pre exposure immunization and subsequent booster every five years.

A.1 Administration by intramuscular route :

Pre-exposure immunization consists of a series of three intramuscular injections of 1 ml each (in deltoid muscle or in the anterolateral region of the thigh in small children) on day 0,7, 21 or 28. A few days variation is not important. It should not be given by intragluteal injection.

A.2 Administration by intradermal route :

Pre-exposure immunization consists of a series of three intradermal injections of 0.1 ml each (side of the deltoid) on days 0, 7, 21 or 28. A few days variation is not important. Vaccine when given intradermally should raise a visible and palpable bleb in the skin and shall only be done where trained personnel is available e.g. hospitals / Rabies Vaccination clinics. In the event that the dose is inadvertently given subcutaneously or intramuscularly or in the event of spillage, a new dose should be given intradermally in nearby site.

B. Post-exposure immunization in unimmunized or incompletely immunized subjects :

As with all vaccines, SURE RAB™ my not protect 100% of people vaccinated**.**

B.1 Administration by intramuscular route :

Post-exposure immunization consists of intramuscular injections of 1 ml each (in deltoid muscle or in the anterolateral region of the thigh in small children) on day 0, 3, 7, 14, 28 & 90 (Optional). It should not be given by intragluteal injection.

B.2 Administration by intradermal route :

Post-exposure immunization consists of intradermal injections of 0.1 ml each at two locations (One in each upper deltoid region, left & right) on day 0, 3, 7 & 28 (Updated Thai Red Cross Schedule 2-2-2-0-2). Vaccine when given intradermally should raise a visible and palpable bleb in the skin and shall only be done where trained personnel is available e.g. hospitals / Rabies vaccination clinics.

C. Post-exposure immunization for previously vaccinated subjects :

Re-exposure following post –exposure treatment or if pre-exposure vaccination was performed (primary vaccination or booster within 5 years previously) administer two booster doses intramuscularly (1ml) / intradermally (0.1 ml at 1 site) on day 0 and day 3. Treatment with rabies immunoglobulin is not necessary. This does not apply to immunodeficient subjects.

If pre or post exposure vaccination was performed more than 5 years before, if it is incomplete, in case of doubt, or in case of neural tissue vaccine used by the subjects, vaccination status is not considered as complete and a full post exposure treatment should be started.

Passive Immunization with Rabies lmmunoglobulin in post exposure subjects Rabies lmmunoglobulin (RIG) is of proven effectiveness as an adjunct to vaccine treatment. Rabies lmmunoglobulin should be administered on day 0 concomitantly with the vaccine, in addition to a full post exposure vaccination series, in category III exposure and for immunodeficient subjects in case of category II/III bite exposure. The sensitivity of the subject to antiserum should be determined prior to its use. Use separate syringe and site for injection of vaccine and rabies immunoglobulin. For more information refer to the package insert of the rabies immunoglobulins used. The rabies immunoglobulin posology is as below:

- Human rabies immunoglobulin.....20IU/kg of body weight.
- Equine rabies immunoglobulin .....40 IU/kg of body weight.

CATEGORY OF BITE	TYPE OF CONTACT	TREATMENT RECOMMENDED
I	Touching and feeding of animals licks on intact skin	None, if reliable case history is available.
II	Nibbling of uncovered skin, minor scratches or abrasions without bleeding	• Wound management • Administer anti rabies vaccine. • For immunodeficient subject administer vaccine and rabies immunoglobulin
III	Single or multiple transdermal bites or scratches, licks on broken skin, contamination of mucous membrane with saliva (i.e. licks), Exposure to bats.	• Wound management • Administer anti rabies vaccine. • Administer rabies immunoglobulin

4.3 Contra indications :-

- Post- exposure immunization – Given the fatal outcome of the declared rabies infection, there are no contra indications to post exposure vaccination.
- Pre- exposure immunization- Allergic **(**Hypersensitive) to any of the vaccine component, in case of acute disease or febrile illness, it is preferable to postpone vaccination.

4.4 Special warnings and precaution for use :

- In case vaccine has not been stored in proper cold chain and or crack in vial, the integrity of pellet/ powder of vaccine could change. Before using the vaccine check for powder/ pellet integrity or discard vaccine if pellet is not visible / shrunk /deformed.
- The vaccine after reconstitution should be shaken gently and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above, being observed, discard the vaccine.
- As with other vaccines, in rare cases anaphylactic shock may occur in susceptible individual. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis. The vaccines should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone & antihistaminic should also be available in addition to supportive measures such as oxygen inhalation.
- Do not administer by intravascular injection.

4.5 Interaction with other medicinal products and other forms of interaction :

The corticosteroids and immunosuppressive treatment may lead to vaccination failure.

4.6 Pregnancy & Lactation :

No cases of harm attributable to use of Rabies Vaccine during pregnancy have been observed to date in mothers or children. It is not known whether Rabies vaccine passes into breast milk.

No risk to the breast-feeding infant has been described to-date. It is advisable to carefully weigh expected benefits against potential risks prior to pre-exposure immunization during pregnancy and breast- feeding.

4.7 Effects on ability to drive and use machines :

Not Applicable.

4.8 Undesirable effects :

As for any active product, there may be more or less moderate and temporary side effects like:

- Pain, induration, erythema, pruritis at the injection site.
- Rare, transient, febrile reactions, headache, malaise, fatigue, nausea.
- Rarely anaphylactic reactions and allergic urticaria, rash may be encountered.
- Pharmacovigilance programme of India (PvPI) has concluded relationship between anti-rabies vaccine and Erythema Multiforme.

4.9 Over dose :-

Not Applicable

5. Pharmacological Properties :-

5.1 Pharmacodynamic Properties :-

Not applicable.

5.2 Pharmacokinetic Properties:-

Not applicable

5.3 Preclinical Safety Data :-

In the pre-clinical studies, no abnormal or adverse effects due to Rabies Vaccine, Human (Cell Culture) IP were noted in animals during the acute toxicity studies as well as long term toxicity studies. The Rabies vaccine, Human (Cell Culture) IP had passed the preclinical studies in animals.

6. Pharmaceutical Particulars :-

6.1 List of excipients :-

Each vial of lyophilized vaccine contains:-

Stabilizer

Polygeline.....10.5 mg
Sucrose..... 25 mg
Potassium L-glutamate..... 0.9 mg
Di Sodium edetate (EDTA)..... 0.25 mg

6.2 Incompatibilities :-

Not applicable

6.3 Shelf life :-

Use the product within 36 months from the date of manufacture.

6.4 Special precaution for storage:-

Store between+2°C to + 8°C (in a refrigerator). Freezing does not damage the lyophilized vaccine.

6.5 Nature & contents of container :-

Materials used for the containerization of Rabies Vaccine, Human I.P. are as follows:

- **Glass Vials :-**
  2 ml clear tubular glass vial (USP type I)

- **Rubber closures :-**

  13 mm Slotted Grey Butyl Unister RFU Sterile Rubber Stopper

- **Aluminium Seals :-**

  13 mm flip off Red (RD-15) aluminium seal.

Materials used for the containerization of vaccine diluent are as follows:

- **Glass vial :-**

  2 ml clear tubular glass vial (USP type I)

- **Rubber Closures: -**

  13 mm non slotted Grey butyl, 'Unister RFU' sterile Rubber stopper.

- **Aluminium Seals :-**

  13 mm flip off white (WE1) aluminium seal.

6.6 Special precautions for disposal:-

No special requirements.

7. Marketing authorization Holder :-

BIO-MED (P) LTD.
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Website : www.biomed.co.in

8. Marketing authorization number :-

a) Form 46 Permission No. MF- 253/2014 dated 20/11/2014.
b) Amendment for Form 46 vide F. No. 12-01/Biomed/14-BD dated 06/06/2016.
c) Amendment for Form 46 vide F. No. 12-58/Biomed/09-BD dated 02/07/2028.

9. Date of first authorization/Renewal of the authorization:-

a) Additional item license No. vide letter No. Drug/837/375 dated 16/01/2015.
b) Additional item license No. vide letter No. Drug/837/5194 dated 08/06/2016.
c) Additional item license No. vide letter No. Drug/837/6975 dated 26/07/2016.
d) Additional item license No. vide letter No. Drug/837/1904 dated 15/02/2017.
e) Additional item license No. vide letter No. Drug/837/3284 dated 19/05/2017.
f) Corrigendum vide letter No. Drug/837/2828 dated 12/09/2018.
g) Renewal of authorization on Form 26-H dated 21/05/2014.

10. Date of Revision of the text:-

January 2024.