SUMMARY OF PRODUCT CHARACTERISTICS

OF

Rabies Vaccine, Human I.P.

Brand Name:SURE RAB™

Manufactured By:

BIO-MED (P) LTD.
C-96, Site No. 1,
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1. Name of the Medicinal Product

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

2. Qualitative and Quantitative Composition

Each single dose lyophilized Rabies Vaccine contains:
Inactivated, Rabies virus……≥ 2.5 IU
Stabilizer: Polygeline, Sucrose, Salts
Diluent : Sterile water for injection I.P……. 1 ml

3. Pharmaceutical Form

Freeze Dried Vaccine with sterile water for injection for reconstitution.

4. Clinical Particulars :-

4.1 Therapeutic Indications:-

For injection in human – infants, children and Adults **(Pre-exposure immunization)**

4.2 Posology and method of administration :-

Reconstitute the freeze-dried lyophilysate, immediately prior to use with entire content of the vaccine diluent provided with the vaccine, gently agitate until lyophilysate is dissolved completely. Dose for adult and infant/child is same.

A. Administration by intramuscular route

Administer by intramuscular route (1 ml) in deltoid muscle or in the anterolateral region of the thigh in small children. It should not be given by intragluteal injection.

A.1. Pre-Exposure Immunization :-

Pre-exposure immunization consists of a series of three intramuscular injections of 1 ml each on day 0, 7, 21 or 28 (A few days variation is not important).

A.2. Booster dose immunization:-

A booster injection should be administered after one yearof first primary Pre-exposure immunization and subsequent booster every five years.

B. Administration by intradermal route

Intradermal vaccination shall only be done where trained personnel is available e.g. Government hospitals /Rabies vaccination clinics.

B.1 Pre-Exposure immunization :-

Intradermal injections of 0.1 ml each on days 0, 7, 21 or 28 (side of the deltoid). A few days variation is not important.

Post-exposure immunization:

In case of exposure to rabies subject who have previously received a complete pre-exposure vaccination (primary vaccination or booster within 5 years previously) use one of the rabies vaccine approved for post-exposure administration: 2 doses on day 0 and day 3.No administration of rabies immunoglobulin is required.

4.3 Contra indications :-

- Hypersensitivity to any of the vaccine component.
- Acute infection or febrile illness.

4.4 Special warnings and precaution for use :-

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 life saving. 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 and antihistaminic should also be available in addition supportive measures such as oxygen inhalation.

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.

- Rarely anaphylactic reactions, urticaria, rash may be encountered.
-Pharmacovigilance Programme of India (PvPI) have concluded relationship between anti-rabies vaccine and Erythema Multiforme.

4.9 Over dose :-

Not Applicable

5. Pharmacological Properties :-

5.1 Pharmacodynamic Properties :-

Not applicable for vaccine as immunizing doses are too less for pharmacodynamics studies

5.2 Pharmacokinetic Properties:-

Evaluation of Pharmacokinetic properties is not required for vaccine.

5.3 Preclinical Safety Data :-

In the preclinical safety Data the Sure Rab^{TM}is found safe

6. Pharmaceutical Particulars :-

6.1 List of excipients :-

Stabilizer: Polygeline, Sucrose, Salts.

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^{o}C to + 8^{o}C (in a refrigerator).

6.5 Nature & contents of container :-

Materials used for the final packing of Rabies Vaccine, Human I.P. are as follows:
Glass Vials :-
USP Type-I clear tubular 2 ml glass vials.

Rubber closures :-
13 mm Grey Butyl Slotted Rubber Stopper (Sterile ready for use).

Aluminium Seals :-
13 mm flip off PK-1 aluminium seals.

Materials used for the final packing of Vaccine Diluent (Sterile Water for Injection I.P.) are as follows:

Glass Vials :-
USP Type-I clear tubular 2 ml glass vials.

Rubber closures :-
13 mm Grey Butyl Rubber Stopper (Sterile ready for use).

Aluminium Seals :-
13 mm flip off WE-1 aluminium seals.

6.6 Special precautions for disposal:-

No special requirements

7. Marketing authorization Holder :-

Bio-Med (P) Ltd.
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E-mail :saryugarg@yahoo.com
Website :www.biomed.co.in

8. Marketing authorization number :-

MF-253/2014

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

20 Nov 2014