1.0 NAME OF THE MEDICINAL PRODUCT

Rabies Vaccine for Human use, Thiomersal Free

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION

On reconstitution each vial of 0.5 ml Lyophilized vaccine contain (single dose):

Purified Beta Propiolactone Inactivated Rabies Virus prepared on Vero cells (Pitman Moore strain of Rabies virus) ≥ 2.5 IU

Maltose up to 1 immunizing dose (5%)

Human Albumin up to 1 immunizing dose (1%)

Diluent:

0.3% w/v Sodium Chloride Injection……..0.5 mL

The diluent of 0.3% Sodium Chloride Injection is procured from M/s Sovereign Pharma Pvt. Ltd, Nani-Daman, India. The manufacturing is done in WHO cGMP compliant facility.

3.0 PHARMACEUTICAL FORM

Vaccine: Lyophilized powder for injection with diluent ampoule

4.0 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pre-Exposure prophylaxis: This vaccine is specially recommended for high risk professionals e.g. Veterinarians, animal care personnel, hunters, doctors, rabies laboratory personnel, production personnel, army personnel and children who are exposed to the risk of rabies.

Post exposure prophylaxis: Treatment of subjects bitten by suspicious rabid animal

4.2 Posology and method of administration

Dose for Children and Audult is 0.5 ml for intramuscular route.

The vaccination schedule should be adopted according to the category of exposure and the immune status of the subject.

- Route of administration: intramuscular injection
- 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.

4.3 Contraindications

INDIRAB *mcf* must not be used in the following cases:

Pre-exposure

- It is preferable to postpone vaccination in severe febrile infection, acute disease, and progressive chronic disease.
- Known hypersensitivity to any of the ingredients of the vaccine.

Post-exposure

- No contraindication for post-exposure vaccination in the case of bites by suspected and rabid animals, as rabies is a fatal disease.

4.4 Special warnings and precautions for use

- Intramuscular injections must be administered by staff trained in this technique.
- Vaccine vials should be stored at temperature between $+2^0$C and $+8^0$C after reconstitution and the total content should be used as soon as possible, at least within 8 hours.
- Do not inject by the intravascular route; make sure that the needle does not enter a blood vessel.
- Immunoglobulin and rabies vaccine must not be mixed in the same syringe or injected at the same site.

- Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Corticosteroids and immunosuppressive treatment may interfere with antibody production and cause vaccine failure. In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be reported to doctor. If any contraindication exists, the risk of prophylactic vaccination should be weighed against those of a possible infection, and if necessary the vaccination should be carried out taking appropriate precautions.

4.6 Pregnancy and lactation

Adequate human data on the use of vaccine during pregnancy or lactation and adequate animal reproductive studies are not available.

It is recommended to postpone pre-exposure prophylaxis during pregnancy. For post-exposure vaccination, pregnancy is not a contraindication, as rabies is a fatal disease.

For the vaccination of subjects at a high risk of infection, the benefit/risk ratio must be assessed before administering the injection.
During pregnancy and lactation, it is recommended to ask your doctor for advice before using the vaccine.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

- Minor local reactions: pain, erythema, oedema, pruritus and induration at the injection point.
- Systemic reactions: moderate fever, shivering, fainting, asthenia, headaches, dizziness, arthralgia, myalgia, gastrointestinal disorders (nausea, abdominal pains).
- Exceptional cases of anaphylactic reactions are observed.

4.9 Overdose

Not Recommended.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Human Rabies vaccine (INDIRAB mcf) being a generic product already in the market with well established literature. Since no novel adjuvant and excipients were used in the formulation of INDIRAB *mcf* vaccine, hence the Pharmacodynamic studies need not necessarily be conducted.

5.2 Pharmacokinetic properties

Evaluation of Pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

Not Applicable

6.0 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Human Albumin and Maltose.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

Three years (when stored at +2° C to +8°C).

6.4 Special precautions for storage

- Do not use the vaccine after expiry date.
- Vaccine vials should be stored between +2^{o}C and +8^{o}C
- After reconstitution the total content **should be used within 8 hours.**
- Do not freeze after reconstitution.
- Keep out of the reach of children.

6.5 Nature and contents of container

Vials of both Vaccine and diluent: type I borosilicate glass.

6.6 Special precautions for disposal

Discard the vaccine if particulate matter observed after reconstitution.

7.0 MARKETING AUTHORISATION HOLDER

Name of the Company: Bharat Biotech International Limited

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E. Mail: info@bharatbiotech.com

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8.0 MARKETING AUTHORISATION NUMBER(S)

Not Applicable at this stage.

9.0 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Not Applicable at this stage.