Registration No 1C 22/50

Importer/Manufacturer Neopharm/ Human Biologicals Institute

SUMMARY OF PRODUCT CHARACTERISTIC

1.NAME OF THE MEDICAL PRODUCT

ABHAYRAB

2.QUALITATIVE AND QUANTITATIVE COMPOSITION

Purified Inactivated Vero Cell Rabies Antigen ≥ 2.5 IU

3.PHARMACEUTICAL FORM

Sterile Powder

4.CLINICAL PARTICULARS

4.1Therapeutic indications

- For active immunization against Rabies both for prophylaxis and post-bite therapy in all age groups of humans.

- For immunizing against Rabies after exposure (after contact with a rabid or suspected rabid animal).See Table 1 for W.H.O. recommendations.

- For prophylactic immunization of all high risk group of persons such as Velerinarians, Municipal workers. Medical and Paramedical personnel. Forest and Zoo personnel, Hunters, Laboratory personnel working with suspected Rabies materials and pet owners.

4.2Posology and method of administration

Reconstitute the freeze-dried vaccine with the diluents supplied along with the vaccine. Administer the reconstituted vaccine (entire quantity of the vial) by deep intramuscular route in the deltoid region or by subcutaneous route. The reconstituted vaccine is to be used immediately and shall not be stored for administration later

4.3Contraindication

As Rabies is a dreaded disease, no contraindications are to be considered in case of post bite therapy.

4.4 Special warnings and precaution for use

1. Concurrent use of immunosuppressive agents like corticosteroids shall be avoided as it may hamper in the development of protective antibodies.

2. In case of severe bites and at the site of injuries nearer to head local infiltration of the wounds with antirabies immunoglobulins is recommended.

3. Delay in the commencement of post-bite therapy, incomplete and irregular therapy can cause failure of protection.

4.5 Interaction with other medical products and forms of interaction

-

4.6 Pregnancy and lactation

-

4.7 Effects on the ability to drive and use machines

-

4.8 Undesirable effects

-

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

1. Human serum albumin 20% w/v

2. Maltose 75% w/v

3.Thiomersal (preservative)

4.Water for injection qs to

6.2 Incompatibilities

-

6.3 Shelf Life

3 year

6.4 Special precautions for storage

To be stored at temperature between 2°C and 8 °C

6.5 Nature and contents of container

-

6.6 Special precautions for disposal and other handling

-

7. MARKETING AUTHORISATION HOLDER

NEOPHARM

8. MARKETING AUTHORISATION NUMBER(S)

22/2534

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 JAN 2007

10. DATE OF REVISION OF THE TEXT

30 JAN 2012