Registration No. 1C 26/53(B)

Importer / Manufacturer: BioNet-Asia Co., Ltd. / Liaoning Cheng Da Biotechnology Co., Ltd.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
SPEEDA™

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vial contains:
Protective power of rabies antigen (Rabies virus L.Pasteur PV-2061 propagated on Vero cell and inactivated by β-propiolactone)……………………………... ≥ 2.5* IU

*Potency is ≥ 2.5 IU before and after heating for 4 weeks at 37°C

Other ingredients
Human serum albumin, Dextran 40
Diluent: Sterile water for injection 0.5 ml

3. PHARMACEUTICAL FORM
Freeze-dried vaccine in vial along with diluent in ampoule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
The vaccine can induce immunity against rabies virus in recipient following immunization, it is used to protect against rabies.

Pre-exposure vaccination: The persons at risk of contacting rabies virus shall be vaccinated following the pre-exposure schedule, such as laboratory personnel handling material contaminated with rabies virus, they should be vaccinated, done the serum test every 6 months, need another booster injection if the antibody titer in the serum is less than 0.5 IU/ml.
The vaccination is also necessary to the veterinarians and their assistants, animal feeders, gamekeepers, hunters, forestry workers, children in enzootic areas, travelers planning to stay in enzootic areas.

Post-exposure: The persons are bitten or scratched by a rabid dog or other rabid animals. The treatment is adapted to the type of wound and the status of the animal.

4.2 Posology and method of administration
To reconstitute the vaccine, introduce the diluent 0.5 ml into the vial of powder and shake thoroughly until the powder is dissolved completely. The solution should be homogenous, clear and free of any particles. Withdraw the solution in a syringe.
1. Intramuscular administration
   The 0.5 ml dose of vaccine shall be injected intramuscularly in the deltoid in adults and in the antero-lateral region of the thigh in young children. Do not inject in the gluteal region.
2. Intradermal administration
   The 0.1 ml dose of vaccine (per site) shall be injected intradermally in deltoid.

Pre-exposure schedule:
- Primary vaccination: 3 injections on Day 0, Day 7, Day 28
- Booster injection 1 year later.
- Booster injection every 5 years.
The injection schedule on Day 28 may be administered on Day 21.
Post-exposure schedule:

1. Auxillary therapy:
   The treatment of wound is very important and must be performed promptly after the bite. It is recommended firstly to wash the wound with large quantity of water and soap and with detergent and then apply 70% alcohol, tincture of Iodine or 0.1% Quaternary Ammonium Solution (provided no soap remains as the two products neutralize each other.) Curative vaccination must be administered under medical supervision and only in rabies treatment centre.

2. Vaccination of non-immunized subjects:
   2.1 Intramuscular schedule (Standard intramuscular regimen: ESSEN)
      Five injections (0.5 ml) will be given intramuscularly on day 0, 3, 7, 14 and 28.
   2.2 Intradermal schedule (Modified TRC-ID regimen, 2-2-2-0-2)
      One dose of vaccine, in a volume of 0.1 ml is given intradermally at two different sites, usually the left and right upper arm on days 0, 3, 7 and 28.
   In the case of type III, anti-rabies immunoglobulin should be administrated as well on day 0. The anti-rabies immunoglobulin (20 IU/kg) should be used as local wound soakage injection as much as possible, with the rest part for muscle injection. The rabies vaccine should be administrated in different injection site.
   In case of the following situation, the vaccine dose should be reduplicated on day 0 and 3.
      - The chronic patients suffered from tuberculosis or hepatocirrhosis have been vaccinated immunoglobulin or antiserum the day before the rabies vaccine injection or earlier.
      - The people whose wounded site is close to central nerve.
      - The patients who suffered from congenital or acquired immunity deficiency.
      - The elders.
      - The people who haven’t been inoculated rabies vaccine after exposure.

3. Vaccination of immunized subjects:
   - The people who have got the pre-exposure or post-exposure full course immunity within one year; they should be administrated one dose of vaccine on day 0 and 3 respectively in case of another exposure.
   - The people who have got the pre-exposure immunity and the booster immunity one year later within three years; they should be administrated one dose of vaccine on day 0 and 3 respectively in case of another exposure.
   - The people who have got the pre-exposure immunity but didn’t get booster injection after one year, or the people who have got post-exposure full course immunity one year before; they should get full course vaccination in case of another exposure.
   - The people who have got the pre-exposure immunity and the booster immunity one year later but it is over 3 years; they should get full course vaccination in case of another exposure.

4.3 Contraindications
   Post-exposure therapy immunization:
   Because rabies is fatal disease, there are no contraindications for immunization, including pregnant woman.
   Pre-exposure prophylaxis immunization:
   The person who is pregnant or in the active period of acute fever is recommended to delay vaccination; the person who has seriously chronic disease, disease of the nervous system, seriously hypersensitive disease or has allergic history of antibiotic, biological product should avoid use.
4.4 Special warnings and precautions for use
1. Intravenous injection is prohibited.
2. The vaccine and anti-rabies immunoglobulin must not be administrated with the same syringe and in the same injection site.
3. Before use, please carefully check package, label, appearance and the validity period.
4. After reconstitution, the freeze-dried rabies vaccine should be administrated as soon as possible.

Special precautions for the intradermal route:
1. It is essential that intradermal administration of this 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.
2. In the event that a dose of vaccine is inadvertently given subcutaneously or intramuscularly, a new dose should be administered intradermally immediately.
3. For the intradermal route a sterile syringe with fixed needle (insulin type) is preferred.
4. 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 a “peau d’orange” (orange peel) appearance. If the vaccine has been injected too deeply and a papule is not seen, the needle should be withdrawn and re-inserted nearby.
5. This vaccine does not contain a preservative, therefore, great care must be taken to avoid contamination of reconstituted vaccine.
6. 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 8 hours after reconstitution or discarded.
7. 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
In the case of corticosteroid and immune inhibitor applied, they can affect antibody to be produced, and cause immunization failed. So such patients need to do the antibody neutralization test between 2nd and 4th week after the last vaccination.

4.6 Pregnancy and lactation
N/A

4.7 Effects on the ability to drive and use machines
N/A

4.8 Undesirable effects
Like other vaccine, the vaccine may cause some adverse reactions to a few individuals.
- Local reactions: like pain, redness, edema, pruritus and induration in the injection site; the symptoms will be alleviated without treatment after injection.
- Systemic reaction: like a little fever, chill, asphyxia, atony, giddy, arthralgia, muscle pain, gastrointestinal disorder.
- The serious adverse reactions like rare anaphylaxis like tetter, nettle rash should be properly treated under the doctor’s instruction.

Besides, any adverse reactions not mentioned in the instruction should be reported timely.

4.9 Overdose
N/A
5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
N/A

5.2 Pharmacokinetic properties
N/A

5.3 Preclinical safety data
N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Human serum albumin, Dextran 40
Diluent: Sterile water for injection 0.5 ml

6.2 Incompatibilities
N/A

6.3 Shelf life
3 years from the date of manufacture.

6.4 Special precautions for storage
Store between +2°C and +8°C (Do not freeze). Do not exceed the expiry date stated on the packaging.

6.5 Nature and contents of container
Pack contains 5 vials of vaccine and 5 ampoules of diluent.

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
BioNet-Asia Co., Ltd.

8. MARKETING AUTHORISATION NUMBER(S)
1C 26/53(B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
December 2, 2010

10. DATE OF REVISION OF THE TEXT