

Registration No. 1C 5/57(B)

Importer / Manufacturer: Biovalys Co., Ltd. / Liaoning Cheng Da Biotechnology Co., Ltd.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

SPEEDA™ Chromatographically Purified Vero Cell Rabies Vaccine (CPRV), Rabies Vaccine for Human Use (Vero cell), Freeze-Dried

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial of freeze-dried vaccine for one immunization dose (0.5 ml) contains: vial contains:
Protective power of rabies antigen (Rabies virus L.Pasteur PV-2061 propagated on Vero cell and inactivated by β -propiolactone)..... $\geq 2.5^*$ IU

*Potency is ≥ 2.5 IU even after exposure at 37°C for 4 weeks

The product does not contain a preservative or antibiotic

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 upper arm.

Pre-exposure schedule:

- 3 injections on Day 0, Day 7, Day 28

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 administered as well on day 0. The anti-rabies immunoglobulin (20 IU/kg) of specific human rabies immune globulin of 40 IU/kg of purified rabies serum of equine origin should be used as local wound soakage injection as much as possible, with the rest part for muscle injection. The rabies vaccine should be administered in different injection site.

3. Vaccination of subjects already fully immunized against Rabies:

- If vaccine administered in less than 6 months of exposure (cell culture rabies vaccine): Then 1 injection on D0 is recommended.
- If vaccine administered in more than 6 months of exposure (cell culture rabies vaccine): Then 2 injections on D0, D3 is recommended.

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 known hypersensitivity to any of the ingredients of the vaccine 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 administered 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 administered 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. 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.
4. This vaccine does not contain a preservative, therefore, great care must be taken to avoid contamination of reconstituted vaccine.
5. 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.
6. 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

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

Box of 1 doses contains: 1 vials of vaccine, 1 ampoules of diluent and 1 disposable syringe.

Box of 5 doses 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

Biovalys Co., Ltd. Bangkok, Thailand.

8. MARKETING AUTHORISATION NUMBER(S)

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

April 4, 2014

10. DATE OF REVISION OF THE TEXT

May 9, 2018