

SUMMARY PRODUCT CHARECTERISTICS

Rabies Vaccine for Human use, (Vero-cell) freeze-dried (Speeda Vaccine)

DESCRIPTION	-
POTENCY	<p>Each vaccine vial contains:</p> <p>Protective activity of rabies antigen $\geq 2.5^*$ IU (Rabies virus L-Pasteur PV-2061 propagated on vero cell and inactivated by β-propio lactone)</p> <p>Human serum albumin.....≥ 5.0mg Dextran..... 18.0mg</p> <p>Each diluents ampoule contains:</p> <p>Sterile water for injection0.5 ml</p> <p>*Even after exposure at 37°C for 4 weeks</p>
THERAPEUTIC INDICATIONS	<p>The vaccine can induce immunity against rabies virus in recipients following immunization, it is used to protect against rabies.</p> <p>Pre-exposure vaccination: the persons at risk of contacting rabies virus shall be vaccinated following the pre-exposure schedule, such as laboratory personnel handling materials contaminated with rabies virus, they should be vaccinated, done the serum test every 6 months, need another booster injections if the anti-body 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.</p> <p>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.</p>
DOSAGE & METHOD OF ADMINISTRATION	<p>To reconstitute the vaccine, introduce the diluents 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 solutions in a syringe.</p> <ol style="list-style-type: none"> 1. Intra-muscular administration: the 0.5 ml dose shall be injected intra-muscularly in the deltoid in antero-lateral region of the thigh in young children. Do not inject in the gluteal region. 2. Intra-dermal administration: the 0.1 ml dose of vaccine (per site) shall be injected intradermally in the upper arm. <p>Pre-exposure schedule: 3 injections on day 0, day 7 and day 28. The injection schedule on day 28 may be administered on day 21.</p> <p>Post-exposure schedule:</p> <ol style="list-style-type: none"> 1. Auxiliary 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: <ol style="list-style-type: none"> 2.1 Intra-muscular schedule 5 injections (0.5ml will be given intra-muscularly on day 0, 3, 7, 14 and 28

	<p>2.2 Intra-dermal schedule 1 dose of vaccine, in a volume of 0.1ml is given intra-dermally at two different sites usually the left and right upper arm on days 0, 3,7 and 28 In case of type 3, anti rabies immunoglobulin should be administered as well on day 0. The anti rabies immunoglobulin 20 IU/kg of specific human rabies immunoglobulin or 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.</p> <p>3. Vaccination of subjects already fully immunized against rabies:</p> <p>3.1 If vaccine administered in less than 6 months of exposure (cell culture rabies vaccine), then one injection on day 0 is recommended.</p> <p>3.2 If vaccine administered in more than 6 months of exposure (cell culture rabies vaccine), then two injections on day 0 and day 3 are recommended.</p>
CONTRAINDICATIONS	<p>Post-exposure therapy immunization: Because rabies is a fatal disease, there are no contraindications for immunization, including pregnant women.</p> <p>Pre-exposure prophylaxis immunization: The person who is pregnant or in the active period of acute fever is recommended to delay the vaccination; the person who has serious chronic disease, disease of the nervous system hypersensitive disease or has a allergic history of antibiotic, biological product should avoid use.</p>
SPECIAL WARNINGS & PRECAUTION FOR USE	<ol style="list-style-type: none"> 1. Intra-venous 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 the package, level, appearance and the validity period 4. After reconstitution, the freeze-dried rabies vaccine should be administered as soon as possible 5. In the event that the dose of vaccine inadvertently given subcutaneously or intramuscularly, a new dose should be administered intra-dermally immediately 6. For the intra-dermal route, 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 intra-dermal injection should result in a raised papule with a “paeu d’orange” (orange peel) appurtenance. If the vaccine has been injected too deeply and a papule is seen, the needle should be withdrawn and reinserted nearby 7. This vaccine does not contain a preservative, therefore, grate care must be taken to avoid contamination of reconstituted vaccine 8. Any reconstituted vaccine should be used as soon as possible 9. It must be stored in a refrigerator at +2 to +8°C and used within 8 hours after reconstitution or discarded 10. The intra-dermal route must not be used in the following instance: <ol style="list-style-type: none"> 1 0.1 Individuals receiving long term corticosteroid or other immune suppressive therapy or chloroquine 10.2 Immunocompromised individuals 10.3 Individuals, particularly children with severe, specially to the head and neck or presenting late for consultation
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER	<p>In the case of corticosteroid and immunoinhibitor applied, they can affect antibody to be produced and cause immunization failure. So such patients need to do the antibody neutralization test between 2nd and 4th week after the last vaccination.</p>

FORM OF INTERACTION	
PREGNANCY & LACTATION	The person who is pregnant or in the active period of acute fever is recommended to delay the vaccination.
UNDESIRABLE EFFECTS	<ol style="list-style-type: none"> 1. Local reactions like pain, redness, edema, pruritus and indurations in the injection site. The symptoms will be alleviated without treatment after injection. 2. Systemic reaction: like a little fever, chill, asphyxia, atony, giddy, arthralgia, muscle pain, gastrointestinal disorder. 3. The serious adverse reactions like rear anaphylaxis like tetter, nettle rash should be properly treated under the doctor's instruction.
STORAGE OF VACCINES	Store between +2°C and + 8°C. DO NOT FREEZE
PRESENTATION	Box of 1 dose contains: 1 vial of 1 dose vaccine, diluents 1 ampoule 0.5ml, and 1 disposable syringe Box of 5 dose contains: 5 vials of 1 dose and 0.5 diluents ampoules
MARKETING AUTHORIZATON HOLDER	Imported and Distributed by: Namsey Pharmaceuticals And Medical Supplies Manufactured by: Liaoning Cheng Da Biotechnology Co., Ltd., Xingfeng Street, Hunnan New District, Shenyang China, 110179
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02658