Package leaflet: Information for the User

SPEEDA™
Rabies Vaccine for Human Use (Vero cell), Freeze-dried

After reconstitution, 1 dose (0.5 ml) contains: Inactivated Rabies Virus (L. Pasteur PV-2061 strain) ……. ≥2.5 IU*
*Even after exposure at 37°C for 4 weeks

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse.
- This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. WHAT SPEEDA™ IS AND WHAT IT IS USED FOR

SPEEDA™ Rabies Vaccine for Human Use (Vero cell), Freeze-dried, contains the Inactivated Rabies Virus (L. Pasteur PV-2061 strain)

Rabies vaccines (Pharmacotherapeutic group) can induce immunity against rabies virus in recipients following immunization, it is used to protect against rabies.

Injection of SPEEDA leads to a specific immune response. Neutralization of the rabies virus by rabies antibodies plays a major role in the protection.

Pre-exposure (PrEP)

WHO recommends PrEP for individuals at high risk of RABV exposure. These include sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure.

A booster injection should be administered when VNA levels fall to < 0.5 IU/ml.

Post-exposure (PEP)

The indication and procedure for PEP depend on the type of contact with the suspected rabid animal and immunization status of the patient. For categories II and III, thorough washing and flushing with soap or detergent and copious amounts of water of all bite

wounds and scratches should be done immediately, or as soon as possible. Depending on the characteristic of the wound, antibiotics, analgesics and a tetanus vaccination may be indicated.

Severity Category of Wound		Recommended Treatment
I	Touching or feeding animals, animal licks on intact skin (no exposure);	None, if reliable case history is available [a]
II	Nibbling of uncovered skin, minor scratches or abrasions without bleeding (exposure);	Administer vaccine immediately Stop treatment if animal remains healthy throughout an observation period of 10 days [b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques. Treat as category III if bat exposure involved.
III	Single or multiple transdermal [c] bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats. (severe exposure)	Administer rabies vaccine immediately, and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulin can be injected up to 7 days after administration of first vaccine dose. Stop treatment if animal remains healthy throughout an observation period of 10 days or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques.

a If an apparently healthy dog or cat in or from a low-risk area is placed under observation, treatment may be delayed.

b This observation period applies only to dogs and cats. Except for threatened or endangered species, other domestic and wild animals suspected of being rabid should be euthanized and their tissues examined for the presence of rabies antigen by appropriate laboratory techniques.

c Bites especially on the head, neck, face, hands and genitals are category III exposures because of the rich innervation of these areas.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SPEEDA™

2.1 Contraindications

Do not use SPEEDA™ for pre-exposure immunization:

- If you are allergic to Inactivated Rabies Virus* (L. Pasteur PV-2061 strain) or any of the other ingredients of this medicine (listed in section 6).
- If you are suffering from acute diseases or chronic diseases at acute episode, you may postpone pre-exposure immunization as appropriate.

- If serious adverse events occur after vaccination, the vaccine should not be administered until the cause is identified.

Do not use SPEEDA™ for post-exposure immunization：

If you are with a definite history of hypersensitivity to any of the ingredients of this vaccine, you should receive an alternative rabies vaccine without this ingredient to continue the original immunization procedure.

2.2 Warnings and precautions

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

As with any vaccine, vaccination with Rabies Vaccine BP may not protect 100% of vaccinated individuals.

In subjects with a history of allergy there may be an increased risk of side-effects and this possibility should be taken into account.

As with all vaccines, appropriate facilities and medication such as epinephrine (adrenaline) should be readily available for immediate use in case of anaphylaxis or hypersensitivity following injection. The vaccine may contain traces of neomycin and betapropiolactone which are used during the manufacturing process. Caution must be exercised when the vaccine is administered to subjects with hypersensitivity to betapropiolactone, neomycin, and other antibiotics of the same class.

If Rabies Immunoglobulin is indicated in addition to Rabies Vaccine BP, then it must be administered at a different anatomical site to the vaccination site.

Rabies Vaccine BP should not be administered to patients with bleeding disorders such as haemophilia or thrombocytopenia, or to persons on anticoagulant therapy unless the potential benefit clearly outweighs the risk of administration. If the decision is taken to administer Rabies Vaccine BP in such persons, it should be given with caution with steps taken to avoid the risk of haematoma formation following injection.

Paediatric population

The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

2.3 Special populations

Pregnancy

Data in literature on limited number of exposed pregnancies do not allow a conclusion on the potential risk of Rabies vaccine for pregnancy or for the health of the foetus/newborn child. Due to the severity of disease, pregnancy is not considered a contraindication to post exposure prophylaxis. If there is substantial risk of exposure to rabies, pre-exposure prophylaxis may also be indicated during pregnancy.

Breastfeeding

Due to the severity of the disease, breast feeding is not considered a contraindication and treatment must not be discontinued. It is not known whether this vaccine is excreted in human breast milk, thus no recommendation on continuation/discontinuation of breastfeeding can be made.

Fertility

Rabies Vaccine BP has not been evaluated for impairment of male or female fertility.

2.4 Other medicines and SPEEDA™

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Immunosuppressive agents or other treatments can interfere with the production of antibodies and lead to weaken or the failure of the vaccination. The response of neutralizing antibody should be monitored timely after vaccination.

2.5 Driving and using machines

No studies have been carried out on the effect of SPEEDA™ on the ability to drive and use machines.

3. HOW TO USE SPEEDA™

3.1 Dose

The recommended dose is 0.5 mL of reconstituted vaccine.

Pre-exposure prophylaxis

The primary pre-exposure immunisation course consists of 3 doses: one at D0, D7 and either D21 or D28.

In immunocompetent individuals, a one-week regimen with 2 doses can be used: one at D0 and D7.

For individuals at continued risk, booster doses should be given in line with official recommendations.

The need for serology testing to detect the presence of rabies virus-neutralising antibodies (≥0.5 IU/ml) should be assessed and conducted, if appropriate, in accordance with official recommendations.

Post-exposure prophylaxis

Post-exposure prophylaxis should be initiated as soon as possible after suspected rabies exposure. In all cases, proper wound care (thorough flushing and washing of all bite wounds and scratches with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure). It must be performed before administration of rabies vaccine or rabies immunoglobulin, when they are indicated.

Post-exposure prophylaxis of previously non-immunised individuals

Vaccine should be administered on D0, D3, D7, D14 and D28 (5 injections of 0.5 mL).

For category III exposure (see Table 1), rabies immunoglobulin should be given in association with vaccine. In this case, the vaccine should be administered contralaterally, if possible.

Vaccination should not be discontinued unless the animal is declared not rabid according to a veterinarian assessment (supervision of animal and/or laboratory analysis).

Post-exposure prophylaxis of previously immunised individuals

Previously immunised individuals should receive one dose of vaccine intramuscularly on both days 0 and 3. Rabies immunoglobulin is not indicated in such cases.

According to WHO recommendation, previously immunised individuals are patients who can document previous complete PrEP (pre-exposure prophylaxis) or PEP (postexposure prophylaxis) and people who discontinued a PEP series after at least two doses of a cell culture rabies vaccine.

Special population- immunocompromised individuals

Pre-exposure prophylaxis

The conventional 3-dose regimen should be used (see subsection "*Pre-exposure prophylaxis*") and serology testing of neutralising antibodies should be performed 2 to 4 weeks after the last dose to assess the possible need for an additional dose of the vaccine.

Post-exposure prophylaxis

Only a full vaccination schedule should be administered. Rabies immunoglobulin should be given in association with the vaccine for both categories II & III exposures (see Table 1).

Paediatric population

Paediatric individuals should receive the same dose as adults (0.5 mL).

3.2 Routes 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.

Intramuscular administration

1 dose (0.5ml) of vaccine is administered by intramuscular route into the deltoid area of the arm for adults and children aged ≥ 2 years, and the anterolateral area of the thigh for children aged < 2 years.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Clinical studies experience

Very common (may affect more than 1 in 10 people): pain, fever, headache, asthenia;

Common (may affect up to 1 in 10 people): tenderness, swelling, rash, vomiting, diarrhoea;

Uncommon (may affect up to 1 in 100 people): induration, erythema;

Post-marketing experience

Cold intolerance, chest tightness, shortness of breath, palpitations, hypersensitivity reaction and dizziness.

Experience on clinical studies and post-marketing surveillance of similar products

Circulatory system disorder; lymphadenopathy (lymph node enlargement); urticaria, hyperhidrosis; myalgia, arthralgia, arthritis; anaphylactic reaction (include

anaphylactic shock); encephalitis, threatened syncope, vertigo, acute disseminated encephalomyelitis; angioedema.

In case of adverse reactions, especially those not mentioned above, please contact your doctor or pharmacist.

5. HOW TO STORE SPEEDA™

Keep out of reach of children.

Expiry date

Do not use this medicine after the expiry date which is stated on the label and box.

Storage conditions

Store between +2˚C and +8˚C. Protect from light. Do not freeze.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

6.1 What SPEEDA™ contains

The active substance is:

After reconstitution, 1 dose (0.5 ml) contains: Inactivated Rabies Virus* (L. Pasteur PV-2061 strain)……. ≥ 2.5 IU

*Even after exposure at 37°C for 4 weeks

The other excipients are:

Human Serum Albumin, Dextran 40, Phosphate Buffered Saline (Sodium chloride, Sodium dihydrogen phosphate dihydrate and disodium hydrogen phosphate dodecahydrate)

Diluent: Sterile water for injection

6.2 What SPEEDA™ looks like and contents of the pack

The pharmaceutical form is powders for injections, the vaccine looks like a white crisp cake.

Lyophilized Vaccine

Single dose in a vial (Neutral Borosilicate Glass) with a stopper (Halogenated Butyl) and a cape (Aluminium-plastic multi-cap).

Diluent

Single dose in an ampoule (Neutral Borosilicate Glass).

Presentations

- Box of 1 dose contains:

  Vaccine 1 vial (@ 1 dose), diluent 1 ampoule (@ 0.5 ml) and 1 disposable syringe

- Box of 5 doses contains:

  Vaccine 5 vials (@ 1 dose) and diluent 5 ampoules (@ 0.5 ml)

6.3 Marketing Authorisation Holder and Manufacturer

Name and address: Liaoning Cheng Da Biotechnology Co., Ltd., No.1, Xinfang Street, Hunnan New District, Shenyang, China.

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

Country: Republic of Armenia

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This leaflet is the initial version.