SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

TRCS SPEEDA
Choromatographically Purifed Vero Cell Rabies Vaccine (CPRV)
Rabies Vaccine for Human Use (Vero Cell), Freeze-Dried

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vaccine vial contains:
Protective power of rabies antigen ..... ≥ 2.5* IU
(Rabies virus L-Pasteur PV-2061 propagated on Vero cell and inactivated by β-propiolactone)
Human serum albumin ..... ≥ 5.0 mg
Dextran 40 .....18.0 mg
Each diluent ampoule contains:
Sterile water for injection ..... 0.5 ml
*Potency is ≥ 2.5 IU even after exposure at 37°C for 4 weeks.
The product does not contain a preservative or antibiotic.

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection

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 contracting 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**

Administration

To reconstitute the vaccine, introduce the diluent 0.5 ml into the vial of power 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 anterio-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, Day7, 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 Ill, anti-rabies immunoglobulin should be administrated as well on Day 0. The rabies vaccine should be administrated in different injection site.

Vaccination of subjects already fully immunized against Rabies:

- If vaccine administered on 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 injection on 00 and D3 are recommended.

4.3 Contraindication

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 us.

4.4 Special warnings and precautions for use

Precaution:

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 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 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 °(to +8 °(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
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

6.2 Incompatibilities
N/A

6.3 Shelf life
3 years

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

6.5 Nature and contents of container
Box of 1 dose contains:
Vaccine 1 vial (@ 1 dose), diluent 1 ampoule (@ 0.5 ml)
Box of 5 doses contains:
Vaccine 5 vials (@ 1 dose) and diluent 5 ampoules (@ 0.5 ml)

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
Queen Saovabha Memorial Institute.
The Thai Red Cross Society
Bangkok 10330, Thailand

8. MARKETING AUTHORISATION NUMBER(S)
1A 3/57 (B)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
March 14, 2014

10. DATE OF REVISION OF THE TEXT
June 2019