Directions for use of Rabies Vaccine (Vero Cell) - Human Use

Constituents and characters:

The vaccine is liquid preparation of Rabies fixed virus grown in Vero cells. After incubation, and harvest, the virus suspension is inactivated, concentrated and purified, to which a suitable stabilizer is then added. It is a whitish clear liquid, containing Thimerosal as preservative.

Indications:

If a person is bitten or scratched by a rabid dog or other rabid animals, regardless of age or sex, the wounds shall be cleaned immediately (flush the wounds repeatedly with clean water or soap water, followed by applying iodine tincture or ethanol for several times) and the exposed person shall be inoculated with the vaccine according to the post-exposure schedule as soon as possible. The person at risk of contacting rabies virus (such as veterinarians, animal breeders, forestry workers, workers in slaughterhouse and staffs in Rabies laboratory) shall be immunized following the pre-exposure treatment schedule.

Function and use:

The preparation can induce immunity against Rabies virus in recipients following immunization. It is used to prevent Rabies in human.

Composition:

Composition of each container having 1.0 ml as single human dose is as follow:

- Purified & inactivated Rabies virus .....2.5 I.U.
- Human Albumin(C.P) 0.5%
- Thimerosal 60-90μg

Dosage & Administrations:

(1) The vaccine shall be shaken homogeneously before use.
(2) The deltoid muscle of the upper arm is the recommended site for I.M. administration. For young children, inoculate the vaccine in the muscle at anterolateral aspect of the thigh.
(3) Post-exposure schedule for immunization: Normally one dose of the vaccine shall be administered to the exposed person on days 0 (the first or the intraday), 3 (the fourth day, analogically henceforth), 7, 14, and 28, consecutively; five doses in total. Children shall be treated in the same way. It is recommended to double the first dose of vaccine in case of one of the following situations:
   i) The exposed person was injected with immunoglobulin or antiserum one month before the day of receiving Rabies vaccine.
   ii) Those receiving congenital or acquired immunodeficiency.
   iii) Those receiving immunosuppressant (including antimalaria drug).
   iv) The elderly or patients with chronic diseases;
   v) Administration of Rabies vaccine becomes available to the exposed persons 48 hours or longer after exposure.

Post-exposure treatment shall be dependent on the following classification of wound severity:

Category I: Those petting animal, licked by animal on intact skins without any breaks—neither wound treatment nor administration of vaccine is necessary.

Category II: Those bitten or scratched by animal on skins but without bleeding; or licked on skins with breaks—vaccine shall be administered following the post-exposure immunization schedule.

Category III: Those with single or multiple biting wounds on skins with bleeding; mucous membrane contaminated by saliva of suspected or confirmed rabid animal—the exposed person shall be treated

immediately with Rabies vaccine, Rabies antiserum (40 I.U./Kg body weight, horse origin) or (20 I.U./Kg body weight, human origin). If anatomically feasible, infiltrate the remaining serum (horse or human origin) as much as possible around the wound(s); test dose should be applied to person for checking hypersensitivity of the person to the antiserum

(4) Pre-exposure immunization schedule: A total of three shots given on days 0,7and 28.

(5) Recommendation of boosters for those immunized with Rabies vaccine previously:

i) Complete post-exposure immunization course was conducted in the recent one year: if bitten by a suspected rabid animal, one dose each given on days 0 and 3 separately.
ii) Complete post-exposure immunization course was conducted in previous year: if bitten by a suspected rabid animal, carry out a complete immunization course again.
iii) Complete post-exposure immunization course was conducted in the last 3 years, and followed by boosters: if bitten by a suspected rabid animal, one dose of vaccine shall be given on days 0 and 3 separately.
iv) Complete post-exposure immunization course and booster(s) was conducted more than 3 years ago: if bitten by a suspected rabid animal, a complete post-exposure immunization course shall be executed.

Adverse Reaction:

After inoculation, mild local or systemic reactions may occur, which could be relieved spontaneously. Occasionally rashes may appear. In case of some serious adverse reactions, such as immediate anaphylactic reactions, angioneurotic edema or urticaria, symptomatic treatment is recommended.

Contraindications:

(1) Because rabies is a fatal disease, there are no contraindications for post-exposure immunization.
(2) For pre-exposure immunization, it is not recommended to immunize eligible individuals with fever, acute disease, serious chronic disease, and with a history of allergic reaction to antibiotics and/or biological products. It is recommended to postpone the administration of the vaccine for women in pregnancy or in lactation, if feasible.

Precautions:

(1) Do not use the vaccine if the vaccine contains any foreign substance or any leakage of container or illegible is found.
(2) Alcoholic drinks, strong tea, pungent food and strenuous exercise shall be avoided after injection of the vaccine.
(3) Do not inject the vaccine in the gluteal region.
(4) Freezing is strictly contraindicated.
(5) Use as per directions of physician.

Storage:

Store and ship at 2-8°C. Protect from light.

Validity period:

18 month. Date of expiry is mentioned on the label of vaccine vial.

Manufactured By:

National Institute of Health, Islamabad