Rabix-VC

Rabies vaccine (human) BP

Presentation

Rabix-vc : Each vial contains lyophilized preparation of purified, inactivated Rabies virus (Pasteur PV-2061 strain) produced on Vero cell. After reconstitution, each ml contains 1 immunizing dose such that the protective power is > 2.5 IU.

Description

Rabix-vc for human use is a freeze-dried preparations of inactivated rabies virus produced on Vero cell. After reconstitution the vaccine is a clear, colorless sterile solution for intramuscular and intradermal use.

Indications and uses

Rabies vaccine is indicated for prophylactic immunization against rabies and treatment of patients following suspected rabies contact.

Pre-exposure immunization

This vaccination is particularly recommended for:

Professional groups exposed to frequent contamination

Veterinary surgeons (including students at veterinary colleges)

Technical personnel working with veterinary surgeons

Laboratory personnel handling material contaminated with rabies virus

Personnel in abattoirs and knackers yards

Taxidermists

Gamekeepers, forestry workers and naturalists in enzootic areas

Infants particularly exposed to the risk of rabies

Post-exposure immunization

Treatment of subjects bitten by rabid animals or those suspected of being so

Treatment of contact subjects

Dosage and Route of Administration:

To reconstitute the vaccine, transfer content of supplied diluent into the vial containing freeze-dried preparation. Do not shake. After reconstitution the solution should be homogeneous, clear and free from any particles. Vaccine must be injected immediately after reconstitution and the syringe should be destroyed after use.

1. Method of administration for intramuscular use

The 1ml dose of Rabix-vc should be given intramuscularly in the deltoid in adults and in the anterolateral aspect of the thigh muscle in children under 1 year. It should not be injected into the gluteal region.

Do not inject intravenously.

2. Method of administration for intradermal use

The 0.1 ml dose of Rabix-vc (per site) should be administered intradermally in the upper arm, over the deltoid.

a) Pre-exposure immunization:

1 ml for children and adults.

Primary-vaccination:

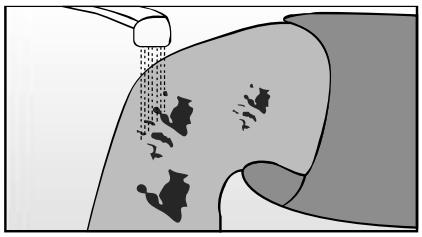
According to the WHO recommendations 1 injection by the intramuscular route on days D0, D7, D21 or D28, followed by a booster dose one year later.

Boosters:

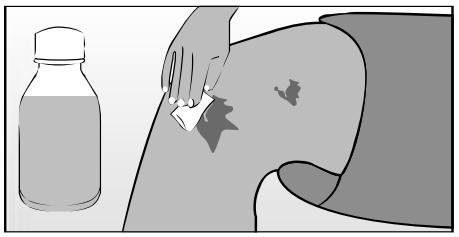
Thereafter, one injection every 5 years or when the titre is found to be less than 0.5 IU/ml

b) Post-exposure immunization:

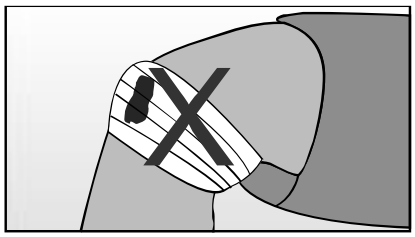
Local treatment of the wound:



1. Prompt and gentle thorough washing with soap or detergent and flushing the wound with running tap water for at least 15 minutes.



2. After washing, disinfectants like either ethanol (700 ml/l) or tincture or aqueous solution of iodine or povidone iodine must be applied.



3. Don't bandage or suture the wound.

Vaccination of non-immunized subjects:

Intramuscular schedules:

One intramuscular (IM) dose comprised of 1 ml.

Standard intramuscular (1-1-1-1-1) regimen:

Day 0: 1 injection of 1 ml

Day 3: 1 injection of 1 ml

Day 7: 1 injection of 1 ml

Day 14: 1 injection of 1 ml

Day 28: 1 injection of 1 ml

Or

Abbreviated multisite (2-1-1) regimen:

Day 0: 2 injections each of 1 ml at separate sites

Day 7: 1 injection of 1 ml

Day 21: 1 injection of 1 ml

Intradermal schedules:

One intradermal (ID) dose is comprised of 0.1 ml.

Thai Red Cross (2-2-2-0-1-1) schedule:

Day 0: 2 injection each of 0.1 ml at separate sites

Day 3: 2 injection each of 0.1 ml at separate sites

Day 7: 2 injection each of 0.1 ml at separate sites

Day 28: 1 injection of 0.1 ml

Day 90: 1 injection of 0.1 ml (optional).

Or

WHO Modified Thai Red Cross (2-2-2-0-2) schedule:

Day 0: 2 injection each of 0.1 ml at separate sites

Day 3: 2 injection each of 0.1 ml at separate sites

Day 7: 2 injection each of 0.1 ml at separate sites

Day 28: 2 injection each of 0.1 ml at separate sites

In case of severe (WHO category 3) wounds, rabies immunoglobulin should be administered as soon as possible with the first dose of rabies vaccine. The anti-rabies immunoglobulin should be used as local wound soakage injections as much as possible, with the rest part for muscle injection. The rabies vaccine should be administered in different injection site.

Vaccination of immunized subjects:

If vaccine administered in less than 5 years of exposure (cell culture rabies vaccine): 2 injections one on each of D0, D3.

If vaccine administered in more than 5 years of exposure or incomplete vaccination: 5 injections on D0, D3, D7, D14 and D28 with administration of immunoglobulin if required.

Post-exposure vaccination must be administered on the basis of severity under medical supervision.

WHO guidelines on post-exposure treatment depending on wound severity

Category	Type of contact with a suspect or confirmed rabid domestic or wild animal or animal available for observation	Recommended treatment
1	Touching or feeding of animal, licks on intact skin.	None, if reliable case history is available.
2	Nibbling of uncovered skin, minor scratches, superficial bites (except on head, neck, shoulder girdle,arms or hands) or abrasions without bleeding, licks on broken skin.	Administer vaccine immediately on Day 0, D3, D7, D14 and D28.Stop treatment if animal remains healthy throughout the observation period of 10 days or if animal is killed humanely and found to be negative by appropriate laboratory techniques.
3	Single or multiple transdermal bites or scratches specially on head, neck, shoulder girdle,arms or hands. Contamination of mucus membrane with saliva (i.e. licks on broken skin).	**Administer rabies immunoglobulin immediately with the first dose of rabies vaccine.** Administer rabies vaccine on Day 0, D3, D7, D14 and D28 or D90 (optional). Stop treatment if animal remains healthy throughout the observation period of 10 days or if animal is killed humanely and found to be negative by appropriate laboratory techniques

Precaution

1. Intravenous injection is prohibited.
2. The vaccine and anti-rabies immunoglobulin must not be administered with 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.
5. Do not shake during and after reconstitution.

Special precaution for the intradermal route:

1. It is essential that intradermal administration of vaccine be administered only by medical staff trained in the ID technique in order to ensure that the vaccine is delivered intradermally and

not subcutaneously.

2. For the intradermal route a sterile syringe with fixed needle (insulin type) is preferred.
3. 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. ID route must not be used in the following conditions :

    Patient receiving immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids.

    Immunocompromised individuals.

Contra-indications

Rabies vaccine is contraindicated in the following cases:

Pre-exposure

Severe fever, febrile infection, acute disease, progressive chronic diseases

Known hypersensitivity reactions to rabies vaccine or any of its components

Post-exposure

No contraindication to post-exposure treatment, because rabies is lethal disease, any contraindication to exposure, treatment should be considered carefully before disqualifying an individual for anti-rabies treatment.

Co-administration

Corticosteroid and immunosuppressive treatment may interfere with antibody production and cause vaccination failure. In these cases, a titration of neutralizing antibodies should be performed.

Pregnancy and Lactation

Pregnancy: The potential risk of administration of rabies vaccine during pregnancy is unknown. Due to the severity of the disease, pregnancy is not considered to be a contra-indication to post-exposure prophylaxis.

Lactation: It is not known whether the vaccine is excreted in human breast milk. Due to the severity of the disease, breast-feeding is not considered a contra-indication.

Side effects

Minor local reactions like pain, erythema, oedema, pruritus and induration at the injection site and lasting to 24-48 hours. Moderate fever, shivering, fainting, asthenia, dizziness, respiratory manifestations (dyspnoea, wheezing), fever, abdominal pain, vomiting and allergic skin reactions (urticaria, rash, itching).

Overdose

Not applicable.

Storage

Keep out of the reach and sight of children

Store at +2 °C to +8 °C. Transportation should also be at +2 °C to +8 °C

Protect from light

Do not freeze

Commercial pack

Rabix-vc : Each box contains 1 vial lyophilized preparation of rabies vaccine, 1 ampoule containing 1 ml WFI and a sterile disposable syringe.