

Rabix-VC

Rabies vaccine (human) BP

Presentation

Rabix-vc: After reconstitution each 1 ml dose contains single dose of Rabies vaccine containing inactivated rabies virus produced on Vero cells. The potency of 1 dose rabies vaccine (1.0 ml) 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 use.

Indications and uses

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

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 administration

a) Pre-exposure immunization

Primary-vaccination:

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

Boosters:

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

b) Post-exposure immunization

Intramuscular schedule:

Non-vaccinated individuals:

Treatment consists of 5 injections.

Intramuscular injections to be given on Day 0, D3, D7, D14 and D28 subsequent to contact with an animal confirmed or suspected of being rabid. In case of severe (W.H.O. category 3) wounds, immunoglobulin should be administered as soon as possible.

Fully vaccinated individuals:

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

Category	Type of contact with a suspect or confirmed rabid domestic 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 or abrasions without bleeding, licks on broken skin	Administer vaccine immediately on Day 0, D3, D7, D14 and D28
3.	Single or multiple trans dermal bites or scratches. Contamination of mucus membrane with saliva(i.e. licks on broken skin	Administer rabies immunoglobulin and vaccine immediately on Day 0, D3, D7, D14 and D28

Method of Administration

Rabix-vc is for intramuscular injection only. Do not inject intravenously.

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

To reconstitute the vaccine, transfer content of supplied diluent into the vial containing freeze-dried powder. 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.

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 lead to 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

Local minor reactions like redness and slight induration at the injection site. 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 oC to +8 oC. Transportation should also be at +2 oC to +8 oC
- Protect from light
- Do not freeze

Commercial Pack

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