BIO-MED PRIVATE LIMITED

PREVENT DISEASES BY VACCINATION

IN SERVICE SINCE 1974

RABIES VACCINE, HUMAN IP
SURE RAB™

DESCRIPTION

It is an inactivated, purified and lyophilized preparation of Pitman Moore strain of rabies virus. The virus is produced on VERO cell culture and inactivated by β-propiolactone. Sure Rab ™ is manufactured as per Indian Pharmacopoeia. The manufacturing facilities meets the requirement as per cGMP guidelines of revised schedule 'M' of the Drugs & Cosmetics Act, Government of India.

COMPOSITION

Each single dose lyophilized vaccine contains :

Inactivated, Rabies virus ..... ≥ 2.5 IU

Stabilizer : Polygeline, Sucrose, Salts

CONTRAINDICATIONS

- Hyper sensitivity to any of the vaccine component.
- Acute infection or febrile illness.

PREGNANCY AND BREAST FEEDING

No cases of harm attributable to use of Rabies Vaccine during pregnancy have been observed to date in mothers or children.

It is not known whether Rabies vaccine passes into breast milk.

No risk to the breast-feeding infant has been described to date. It is advisable to carefully weigh expected benefits against potential risks prior to pre-exposure immunization during pregnancy and breast-feeding.

PRECAUTIONS

The vaccine after reconstitution, should be shaken gently and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above, being observed, discard the vaccine.

As with other vaccines, in rare cases anaphylactic shock may occur in susceptible individual. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be life saving. It should be used at the first suspicion of anaphylaxis. The vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone and antihistaminic should also be available in addition supportive measures such as oxygen inhalation.

DRUG INTERACTIONS

The corticosteroids and immunosuppressive treatment may lead to vaccination failure.

SIDE EFFECTS

As for any active product, there may be more or less moderate and temporary side effects like:

- Pain, induration, erythema, pruritus at the injection site.
- Rare, transient, febrile reactions.
- Rarely anaphylactic reactions, urticaria, rash may be encountered.
- Pharmacovigilance Programme of India (PvPI) have concluded relationship between anti-rabies vaccine and Erythema Multiforme.

STORAGE & PRESENTATION

Store between +2°C to + 8°C (in a refrigerator). Combo Pack : Contains freeze dried vaccine vial, 1 ml of sterile water for injection IP, sterile disposable syringe with needle.

In case vaccine have not been stored in proper cold chain and or crack in vial, the integrity of pellet/powder of vaccine could change. Before using the vaccine check for powder/pellet integrity and discard vaccine if pellet is not visible/shrunk/deformed.

VACCINATION GUIDELINES

Current W.H.O guidelines may be consulted for Rabies Vaccination/immunization.

Pre-exposure immunization

The vaccine is recommended for the prevention of Rabies in subjects at a continuous risk of exposure. A serological test is recommended (every 6 months) in subjects at risk of continuous exposure. For subject at frequent risk WHO recommends antibody titre estimation annually. If titres are below 0.5 IU/ml, one booster dose should be administered.

DOSAGE AND ADMINISTRATION

Reconstitute the freeze-dried lyophilisate, immediately prior to use with entire content of the vaccine diluent provided with the vaccine, gently agitate until lyophilisate is dissolved completely. Dose for adult and infant/child is same.

A. Administration by intramuscular route

Administer by intramuscular route (1ml) in deltoid muscle or in the anterolateral region of the thigh in small children. It should not be given by intragluteal injection.

A.1 Pre-exposure Immunization

Pre-exposure immunization consists of a series of three intramuscular injections of 1ml each on days 0,7, 21 or 28 (A few days variation is not important).

A.2 Booster dose immunization

A booster injection should be administered after one year of first primary Pre-exposure immunization and subsequent booster every five years.

B. Administration by intradermal route

Intradermal vaccination shall only be done where trained personnel is available e.g. hospitals / Rabies vaccination clinics.

B.1 Pre-exposure immunization

Intradermal injections of 0.1 ml each on days 0, 7, 21 or 28 (side of the deltoid). A few days variation is not important.

Post-exposure Immunization

In case of exposure to rabies subject who have previously received a complete pre-exposure vaccination (primary vaccination or booster within 5 years previously) use one of the rabies vaccine approved for post-exposure administration : 2 doses on day 0 and day 3. No administration of rabies immunoglobulin is required.

Manufactured & Marketed by :

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