

SUMMARY PRODUCT CHARECTERISTICS

Rabies vaccine, human. Abhayrab

DESCRIPTION	Freeze dried Purified Inactivated Rabies Vaccine prepared on Vero cells(L.Pasteur 2061/Vero Rabies strain). Thiomersal is added as preservatives. Rabies is an acute viral disease which causes fatal encephalomyelitis in virtually all the warm blooded animals including man. The virus can be found in wild and domestic animals and is transmitted to other animals and humans through their saliva(i.e bites, scratches, licks on broken skin and mucous membrane)														
POTENCY	Freeze-dried Vaccine: 1 immunizing dose contains the protective activity of equal to or greater than 2.5 International Units (IU) . Rabies Virus (L.Pasteur 2061/VERO) propagated on Vero cell line inactivated with beta-propiolactone. Thiomersol0.015% w/v added as preservative. Maltose and Human Serum Albumin.....q.s. as stabilizer.														
THERAPEUTIC INDICATIONS	<p>Pre Exposure vaccination: All high risk groups of personnel such as veterinarians, municipal workers, medical and paramedical personnel, forest and zoo personnel, animal handlers. Laboratory personnel working with suspected rabies materials and pet owners. Persons staying or visiting in rabies endemic areas.</p> <p>Post- Exposure vaccination: Persons after contact/bite by a suspected case of or a rabid animal</p> <table border="1" data-bbox="483 1014 1372 1896"> <thead> <tr> <th data-bbox="483 1014 703 1136">Category</th> <th data-bbox="708 1014 1003 1136">Type of contact with suspected or confirmed rabid animal</th> <th data-bbox="1008 1014 1372 1136">the Course of action to be followed</th> </tr> </thead> <tbody> <tr> <td data-bbox="483 1142 703 1226">I</td> <td data-bbox="708 1142 1003 1226">Touching or feeding of animal,</td> <td data-bbox="1008 1142 1372 1226">None, if reliable case history licks on intact skin available</td> </tr> <tr> <td data-bbox="483 1232 703 1591">II</td> <td data-bbox="708 1232 1003 1591">Nibbling of uncovered skin, minor scratches or abrasion</td> <td data-bbox="1008 1232 1372 1591">Administer vaccine immediately. Stop the treatment if the without bleeding, licks on animal remains healthy for broken skin a period of 10 days or has been killed humanely and found to be negative for Rabies by appropriate laboratory techniques.</td> </tr> <tr> <td data-bbox="483 1598 703 1890">III</td> <td data-bbox="708 1598 1003 1890">Single or Multiple transdermal bites or scratches with saliva immunoglobulins and (i.e.licks)</td> <td data-bbox="1008 1598 1372 1890">Administer rabies vaccine immediately. Stop treatment if the animal remains healthy throughout the observation period of 10 days or if animal is killed humanely and found to be negative for rabies by appropriate laboratory</td> </tr> </tbody> </table>			Category	Type of contact with suspected or confirmed rabid animal	the Course of action to be followed	I	Touching or feeding of animal,	None, if reliable case history licks on intact skin available	II	Nibbling of uncovered skin, minor scratches or abrasion	Administer vaccine immediately. Stop the treatment if the without bleeding, licks on animal remains healthy for broken skin a period of 10 days or has been killed humanely and found to be negative for Rabies by appropriate laboratory techniques.	III	Single or Multiple transdermal bites or scratches with saliva immunoglobulins and (i.e.licks)	Administer rabies vaccine immediately. Stop treatment if the animal remains healthy throughout the observation period of 10 days or if animal is killed humanely and found to be negative for rabies by appropriate laboratory
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DOSAGE & METHOD OF ADMINISTRATION	<p>For intramuscular: Reconstituted vaccine of 0.5mL to be administered by deep intramuscular route in the deltoid region in adults and in anterolateral aspects of thigh in childrent.</p> <p>For intradermal: Reconstituted vaccine of 0.1mL to be administered at two different lymphatic drainage sites usually the left and right upper arm. Vaccine administered intradermally must raise a visible and palpable”bleb” in the skin. Aseptic technique and sterile needle and syringe must be used to draw up vaccine for each patient and for each dose. The remainder can be used for another patient, provided that the vial is stored in a refrigerator at +2°C to +8° C and the total content are used within 6hours.</p> <p>Immunization Schedule: For Intramuscular:</p> <ul style="list-style-type: none"> • Pre – Exposure: 0.5mL of reconstituted vaccine on 0,7 and 21or 28th day followed by annual booster vaccination • Post Exposure: <ul style="list-style-type: none"> ○ For a new case: 0.5 ml of reconstituted vaccine on days 0,3,7,14 and 28. ○ For previously immunized individuals: they should receive a two booster series on days 0 and 3. The administration of passive immunization is not required. ○ For immunocompromised individuals: they should definitely receive rabies immunoglobulin in addition to a full post – exposure vaccination series as listed above even in category II bite. <p>For intradermal:</p> <ul style="list-style-type: none"> • Pre-Exposure: two doses of reconstituted vaccine of 0.1mL each on 0,7 and 21 or 28th day followed by annual booster vaccination. • Post Exposure: <ul style="list-style-type: none"> ○ For a new case: 2- site Intradermal regimen(2-2-2-0-2): Two doses of reconstituted vaccine of 0.1mL each on days 0,3,7 and 28.vaccine administered intradermally raises visible and palpable bleb in the skin.intradermal injections must be carried by staff trained in this technique ○ For previously immunized individuals: they should receive a two booster series on days 0 and 3. The administration of passive immunization is not required. ○ For immunocompromised individuals: they should definitely receive rabies immunoglobulin in addition to a full post – exposure vaccination series as listed above even in category II bite.
CONTRAINDICATIONS	<p>Post-exposure immunization As Rabies is a dreaded disease; no contraindications are to be considered in case of post-bite therapy.</p>

	<p>Pre-exposure immunization In case of pregnancy or acute febrile illness, the vaccination should be postponed.</p>
SPECIAL WARNINGS & PRECAUTION FOR USE	<p>Precautions:</p> <ul style="list-style-type: none"> • Concurrent use of immunosuppressive agents like corticosteroids should be avoided as it may hamper in the development of protective antibodies. • In case of category III bites as per WHO classification (see table 1) anti rabies immunoglobulin is recommended along with the first dose of rabies vaccination. • Use intramuscular route in cases of severe or delayed cases of category III bites on day '0' • Delay in the commencement of post-bites therapy, incomplete and irregular therapy can cause failure of vaccination and protection against rabies. • If anti-malarial chemo prophylaxis (e.g with chloroquine) is being given concurrently vaccine should be administered through intramuscular route only. • Vaccine should never be administered into the gluteal region, where absorption is unpredictable. • As with any injectable vaccine , hypersensitivity or anaphylaxis can occur with Abhayrab and thus inj. Adrenaline(1:1000) and other anti- histaminics should be ideally available during vaccination. • Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine. <p>Warnings:</p> <ul style="list-style-type: none"> • The vaccine should never be given by intravascular route. • Same syringe or site should not be used for administering the immunoglobulin and the vaccine.
PREGNANCY & LACTATION	<p>Pregnancy Category C. Animal reproductive studies have not been conducted with Abhayrab. It is also not known whether Abhayrab can cause fetal abnormalities when administered to pregnant women or can affect reproduction capacity. Abhayrab should be given to a pregnant woman only If clearly needed. Use In Lactation: As Rabies is always fatal in humans, there are no contraindications. It can be used in lactation in case of suspected rabid contamination. Use In Children's: As Rabies is always fatal, there is no age limitation. It can be used in all ages of children's in case of suspected rabid contamination.</p>
UNDESIRABLE EFFECTS	<p>Local minor events: Mild pain, erythema, induration, pruritus, rash, oedema at the site of injection. Systemic mild events: Mild fever, headache, Myalgia, malaise. Very rarely: High fever, gastrointestinal disorders, lymphadenopathy, arthritis and anaphylaxis.</p>
STORAGE OF VACCINES	<p>To be stored at temperature between 2⁰C and 8 °C</p>

PRESENTATION	<p>Abhayrab is available as:</p> <ul style="list-style-type: none"> • Freeze dried vial with 0.5mL sterile diluents IP. • Combo pack: contains freeze dried vaccine vial, 0.5mL of sterile diluent IP, sterile disposable syringe with needle and alcohol swab. • Freeze dried vial with 1.0mL sterile diluent IP • Combo pack: contains freeze dried vaccine vial, 1.0 mL of sterile diluent IP, sterile disposable syringe with needle and alcohol swab.
MARKETING AUTHORIZATON HOLDER	<p>Karma Pharmaceutical and Medical supplies Manufactured by: Human biological Institute, Kozhipannai, India</p>
PRODUCT REGISTRATION NUMBER	BHU-DRA/BO2899