طبقا لقرار اللجنة العلمية لتخصصية الأطفال ولقاحات وتطعيم بليس للمستحضرات طبية ومشتقات لدم بجلستها في ٢٠١٩/١١/٢٤

Pack insert -Egypt

Intradermal administration must be carried out by staff trained in this technique.
Rabies immunoglobulin should be administered preferably as soon as possible after initiation of post exposure prophylaxis in all cases of category III bites but not beyond 7 days from the first dose of vaccination. In immuno compromised cases, even category II bites require administration of rabies immunoglobulin.

B. Previously Fully Immunised Individuals:

Patients who have previously received a complete course of primary vaccination (pre- or post- exposure) should receive only two doses of Abhayrab® as described below:

Intramuscular route: One dose of 0.5 ml of the reconstituted vaccine intramuscularly on days 0 and 3.

Intradermal route: One dose of 0.1 ml of the reconstituted vaccine intradermally at one site on days 0 and 3.

Administration of rabies immunoglobulin is not required in previously fully immunized individuals (with proof of the immunization).

POSSIBLE SIDE EFFECTS OF ABHAYRAB®

Like all medicines, Abhayrab® vaccine may also have side effects. The following side effects may occur:
Local minor events: Mild pain, erythema, induration, pruritus, rash, oedema at the site of injection.
Systemic mild events: Mild fever, headache, myalgia, malaise, nausea, dizziness.
Rarely to Very rarely: Moderate to High fever, gastrointestinal symptoms, lymphadenopathy, erythema multiforme, arthritis and anaphylaxis.
If you get any side effects, talk to your doctor or nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

HOW TO STORE ABHAYRAB®

- Keep out of the reach and sight of children.
- Store in the refrigerator (+2°C to +8°C). Do not Freeze.
- After reconstitution, the vaccine should be used immediately.
- Do not use after expiry date on the box

SHELF LIFE: 3 years or 36 months form the date of manufacture.

COMPOSITION:

Purified lyophilized Rabies antigen derived from Rabies virus (L. Pasteur 2061/Vero Strain propagated in Vero Cells) Inactivated.
Potency : ≥ 2.5 I.U per vial.
Stabilizers : Maltose and Human Albumin... q.s.
Preservative : Thiomersal 0. 01% w/v.

PRESENTATION:

1. Combo pack: Contains Freeze dried vaccine vial, 0.5mL of sterile diluent BP & sterile disposable syringe with needle
2. Combo pack: Contains 5 No's of vaccine vials, 5 ampoules of 0.5 mL diluents BP & Literature.

Manufactured and Marketed by :

Human Biologicals Institute
(A division of Indian Immunologicals Ltd)
Kozhipannai, Pudumund (P.O), Dr. Basavaiah Nagar,
Udhagamandalam, PIN: 643007 TAMILNADU, INDIA

PLL0445/02/20

REFERENCES

1. WHO TRS No. 1012 (WHO Expert Consultation on Rabies, Third Report)
2. WHO Technical Report Series 982, WHO EXPERT CONSULTATION ON RABIES
3. NCDC, India, Guidelines (National Guidelines for Rabies Prophylaxis and Intra-dermal Administration of Cell Culture Rabies vaccines), 2015

Warning:	Caution:
To be sold by retail on the prescription of a Registered Medical Practitioner only.	Do not use if any particulate matter is observed after reconstitution.

® Registered Trade Mark.

For the use of Registered Medical Practitioner or Hospital or Laboratory only

RABIES VACCINE B.P.'Rab'

RABIES VACCINE FOR HUMAN USE PREPARED IN CELL CULTURES

(PURIFIED VERO CELL RABIES VACCINE)

Abhayrab®

Please read this entire package leaflet carefully before getting vaccinated.
Keep this package leaflet till you have completed your vaccination schedule. You may need to read it again. You should follow your doctor's or nurse's or pharmacist's recommendations carefully. If you need more information or advice, ask your doctor or nurse or pharmacist. Ensure that you have completed the entire vaccination schedule. Otherwise, you may not be fully protected. This vaccine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

WHAT IS ABHAYRAB® AND WHAT IT IS USED FOR

Abhayrab® is a vaccine and is indicated for active immunization against rabies. It can be used before or after exposure, as a primary vaccination or as a booster dose.

a) Pre-exposure immunization (Prior to exposure to rabies virus) Particularly recommended for high risk groups of people such as:

- Laboratory staff handling the virus and infected material
- Clinicians and persons attending to human rabies cases
- Veterinarians, veterinary students
- Animal handlers and catchers
- Wildlife wardens, forest officials
- Quarantine officers
- Travelers from rabies free areas to rabies endemic areas.
- For residents in an endemic setting with limited access to timely, and adequate post-exposure prophylaxis.

b) Post-exposure treatment (after suspected exposure to rabies virus)

Recommended for persons after contact/ bite by a suspected case of or a rabid animal and/or persons suspected to have been exposed to live rabies virus or to caves with high density of rabies infected bats.

Post exposure treatment includes local wound care, passive immunization with rabies immunoglobulins and vaccination, depending upon the category of exposure and should be given as per the recommendations provided by WHO as mentioned in table 1.

BEFORE YOU USE ABHAYRAB®

Contraindications

- In case of pre-exposure prophylaxis, rabies vaccination is contraindicated in severe febrile illness, acute or chronic progressive illness and known hypersensitivity to any of the components of the vaccine.
- As Rabies is a fatal disease, there are no contraindications in case of post-exposure prophylaxis.
- In case of previous severe reaction to any component of Abhayrab vaccine, during pre-exposure or post-exposure prophylaxis, further vaccination with Abhayrab is contraindicated and vaccine product should be changed.

Table 1: WHO recommendations for Post-Exposure prophylaxis according to type of exposure[1]

Category of exposure	Type of exposure to a domestic or wild animal suspected or confirmed to be rabid or animal unavailable for testing	Recommended post-exposure prophylaxis
Category I	Touching or feeding animals, licks on intact skin (no exposure)	None, if reliable case history is available[a] (in case of uncertainty, vaccine to be administered)
Category II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding(exposure)	Administer vaccine immediately. Stop treatment if animal remains healthy throughout an observation period of 10 days[b] or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques. Treat as category III if bat exposure involved.
Category III	Single or multiple transdermal[c] bites or scratches, contamination of mucous membrane or broken skin with saliva from animal licks, exposures due to direct contact with bats (severe exposure).	Administer rabies vaccine immediately, and rabies immunoglobulin, preferably as soon as possible after initiation of postexposure prophylaxis. Rabies immunoglobulin can be injected up to 7 days after administration of first vaccine dose. Stop treatment if animal remains healthy throughout an observation period of 10 days or is proven to be negative for rabies by a reliable laboratory using appropriate diagnostic techniques.

[1] If an apparently healthy dog or cat in or from a low-risk area is placed under observation, treatment may be delayed.
[2] This observation period applies only to dogs and cats. Except for threatened or endangered species, other domestic and wild animals suspected of being rabid should be euthanized and their tissues examined for the presence of rabies antigen by appropriate laboratory techniques.
[3] Bites especially on the head, neck, face, hands and genitals are category III exposures because of the rich innervation of these areas.

Warnings:

- *The vaccine should never be administered by intravascular route.*
- Only the diluent supplied along with the vaccine vial should be used for reconstitution.
- Same syringe or site should not be used for administering the immunoglobulin and the vaccine.
- Keep out of reach of children.

Precautions:

- Concurrent use of immunosuppressive agents like corticosteroids should be avoided as it may hamper the development of protective antibodies.
- When rabies immunoglobulin is recommended along with the first dose of rabies vaccination, it has to be administered with a different syringe & needle and a site away from the site of vaccination.
- Delay in the commencement of post-bite therapy, non-adherence to vaccination schedule and cold chain can cause failure of vaccination and inadequate protection against rabies.
- 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 medications including anti- histaminics should be readily available during vaccination.
- Alcohol and other disinfecting agents must be allowed to evaporate from the skin before administration of the vaccine.
- The vaccine recipients should be kept under medical supervision for at least 30 minutes after vaccination to monitor for any immediate undesirable effects.

Interaction with other medicaments and other forms of interaction

- In patients receiving corticosteroids or other immunosuppressive therapy or antimalarial medications or those with congenital or acquired immunodeficiency, the response to the vaccination may be reduced or absent.
- Rabies immunoglobulin should be administered at the recommended dose only. The immunoglobulin should neither be given at higher nor lower doses than recommended, nor should it be repeatedly administered, as this may attenuate the effects of concomitantly administered rabies vaccine.

Driving and Using Machines

Post-vaccination dizziness has been frequently reported. This can temporarily affect ability to drive and use machines.

Pregnancy and Lactation

In suspected cases of post exposure, considering the severity and fatal implications of the disease, pregnancy and lactation are not contraindications for vaccination with Abhayrab®.

HOW TO USE ABHAYRAB®

Reconstitution:

Prior to use, reconstitute the lyophilized vaccine with the 0.5 ml diluent.
Any reconstituted vaccine should be used as soon as possible. Any leftover amount must be stored in a refrigerator at +2°C to +8°C and used within 6 hours of reconstitution. If not maintained at +2°C to +8°C and / or been stored for more than 6 hours, the vaccine must be discarded.

Posology and method of administration[1,2]

Intramuscular route of immunization:

Reconstituted vaccine of 0.5 ml to be administered by deep intramuscular route in the deltoid region in adults & older children and in anterolateral aspect of thigh in infants and younger children.

Intradermal route of immuniation :

0.1 ml each of the reconstituted vaccine to be administered intradermally in upper arm. Vaccine administered intradermally must raise a visible and palpable 'bleb' in the skin. Aseptic technique and a separate sterile needle and syringe must be used to draw up vaccine for each patient and 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 is used within 6 hours.

The vaccine should never be administered by intravascular route.

PRE-EXPOSURE IMMUNIZATION SCHEDULE

Intramuscular Route :

One immunization dose 0.5 ml of the reconstituted vaccine on days 0, 7 and 21 or 28.

Intradermal Route:

One intradermal injection of 0.1 ml of reconstituted vaccine on days 0, 7 and 21 or 28.

Booster Doses :

Only people whose occupation puts them at continual or frequent risk of exposure should receive periodic booster doses (0.5 ml for intramuscular route of administration/ 0.1 ml at single site for intradermal route of administration) whenever the rabies virus neutralizing antibody titre drops below 0.5 IU/ml.

POST - EXPOSURE TREATMENT

A. Unimmunized or Previously Incompletely Immunized Individuals:

Intramuscular route of administration (ESSEN Regimen): One single dose (0.5 ml of the reconstituted vaccine) of vaccine each on days 0, 3, 7, 14 and 28 ('0' being the day of receiving the first dose of vaccination).

Intradermal route of administration (Updated Thai Red Cross regimen): One intradermal injection of 0.1 ml of reconstituted vaccine each over left and right deltoid area on days 0, 3, 7 and 28 ('0' being the day of receiving the first dose of vaccination). Vaccine administered intradermally raises a visible and palpable "bleb" in the skin.