For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only.

RABIES VACCINE B.P 'Rab/Vac'

1 dose for Human Use

Purified Vero Cell Rabies Vaccine

Abhayrab

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Purified Inactivated Rabies Vaccine prepared on Vero cells. For the prophylactic or post exposure immunization. Prepared using L.Pasteur 2061/Vero Rabies strain. Clinical studies with Abhayrab shows neutralizing antibody responses both after primary and secondary immunizations.

COMPOSITION PER SINGLE DOSE

Freeze-dried Vaccine : 1 immunizing dose contains the protective activity of equal to or greater than 2.5 International Units (IU) even after exposure at 37°C for one month.

Rabies Virus (L.Pasteur 2061/VERO) propogated on Vero cell line inactivated with beta-propiolactone. Thiomersol @ 0.01% added as preservative.

Maltos : q.s. per immunizing dose.
Human Serum Albumin : q.s. per immunizing dose.

The antibiotics Neomycin, Kanamycin and Polymixin B sulphate used in the cell and virus cultures are eliminated to the greatest extent during purification procedures and cannot be detected in the final vaccine.

INDICATIONS

- For active immunization against Rabies both for prophylaxis and post-bite therapy in all age groups of humans
- For immunizing against Rabies after exposure (after contact with a rabid or suspected rabid animal). See Table-1 for W.H.O. recommendations
- For prophylactic immunization of all high risk group of persons such as Veterinarians, Municipal workers, Medical and Paramedical personnel, Forest and Zoo personnel, Hunters, Laboratory personnel working with suspected Rabies materials and Pet owners.

DOSAGE

Prophylaxis: Three immunizing doses on 0, 7 and 21 or 28 days followed by annual booster. Post-Exposure: One immunizing dose on post exposure days 0, 3, 7, 14, 28 and 90 each.

ADMINISTRATION

Reconstitute the freeze-dried vaccine with the diluent supplied along with the vaccine. Administer the reconstituted vaccine (entire quantity of the vial) by deep intramuscular route in the deltoid region or by subcutaneous route. The reconstituted vaccine is to be used immediately and shall not be stored for administration later.

INCOMPATIBILITIES

None

CONTRAINDICATIONS

Post-exposure immunization

As Rabies is a dreaded disease; no contraindications are to be considered in case of post-bite therapy.

Pre-exposure immunization

In case of pregnancy or acute febrile illness, the vaccination should be postponed.

SPECIAL CONDITIONS

Use In Pregnancy

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 a pregnant women or can affect reproduction capacity. Abhayrab should be given to a pregnant women 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.

CAUTIONS

1. Concurrent use of immunosuppressive agents like corticosteroids shall be avoided as it may hamper in the development of protective antibodies.
2. In case of severe bites and at the site of injuries, nearer to head local infiltration of the wounds with antirabies immunoglobulins is recommended.
3. Delay in the commencement of post-bite therapy, incomplete and irregular therapy can cause failure of protection.

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STORAGE

To be stored at temperatures between +2^{O}C to +8^{O}C. Do not freeze.

PRESENTATION

Box of 1 dose vial along with Diluent Ampoule (0.5 ml), Sterile disposable syringe with needle and vaccination card.

Rabies Antiserum I.P
AbhayRIG

Table 1 Guide for post exposure treatment (W.H.0. Recommendations)

Category	Type of contact with the suspected or confirmed rabid animal	Course of action to be followed
I	Touching or feeding of animal, licks on intact skin	None, if reliable case history available
II	Nibbling of uncovered skin, minor scratches or abrasion without bleeding, licks on broken skin	Administer vaccine immediately. Stop the treatment if the animal remains healthy for 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 (i.e.licks)	Administer rabies immunoglobulins and 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 techniques.

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For The Use Of Registered Medical Practioner Only

Elovac - B®

Hepatitis B Vaccine B.P(r DNA)

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DESCRIPTION

Elovac-B® (Recombinant Hepatitis - B vaccine) is a noninfectious recombinant DNA vaccine. It is a sterile suspension of purified major surface antigen of Hepatitis B virus (HBV). The Hepatitis B surface antigen (HBsAg) is produced from cultures of genetically engineered ***Pichia pastoris***, containing the gene that codes for the HBsAg. The HBsAg protein released by disruption of ***Pichia pastoris*** cells is purified by various physiochemical methods. The purified antigen is adsorbed on Aluminium hydroxide gel to get bulk vaccine. The vaccine does not contain any material of human or animal origin.

Elovac-B® is commercially available as a sterile suspension, ready to use for I.M.injection. The vial must be shaken well before administration.

Paediatric & Adolescent dose: Each 0.5ml dose contains 10mcg of Hepatitis B surface antigen (purified) adsorbed on 0.25mg Aluminium as Aluminium hydroxide and 0.025mg of Thiomersal as preservative.

Adult dose

Each 1 ml adult dose contains 20 mcg of Hepatitis B surface antigen (purified) adsorbed on 0.5 mg Aluminium as Aluminium hydroxide and 0.05mg of Thiomersal as preservative.

CLINICAL PHARMACOLOGY

Elovac-B® generates specific protective immune response against HBsAg. For protection against HBV infection the anti-HBsAg titre (Anti-HBs antibodies) should be more than or equal to 10 mIU/ml.

INDICATIONS AND USAGE

Elovac-B® Vaccine is indicated for immunization against infection caused by all known subtypes of Hepatitis B virus.

Routine vaccination

New born, infants, children and adolescents.

Vaccination of defined high risk populations

High risk populations

1. People who have a job that involves contact with human blood (Ex: Health care personnel, Military personnel etc.).
2. Travelers to area where Hepatitis B is common.
3. Injectable drug abusers.
4. Patients who may require multiple blood transfusions.
5. Persons originating from areas of high endemicity.
6. Persons who have sex with someone infected with HBV
7. Persons who have sex with more than one partner.
8. Men who have sex with men.
9. People who live in the same house with someone who has chronic HBV infection.
10. Infants born to HBV positive mothers.

CONTRAINDICATIONS

Elovac-B® Should not be administered to any person who has experienced a hypersensitivity reaction to any component of any Hepatitis B recombinant DNA vaccine.

Elovac-B® Should not be administered to subjects with severe febrile infections.

WARNINGS

Elovac-B® may not prevent infection, if the vaccinee, at the time of immunization was harboring an unrecognized Hepatitis B infection.

Not all vaccinees respond in the same manner to a given vaccine. The immune response may be dependant upon many factors. Some are mentioned below. Age over 40 years, Gender: Male, Smokers, Obese individuals, patients with immunodeficiency diseases or those receiving immuno-suppressive therapy or those who received the vaccine on the gluteal region, may have an unsatisfactory antibody titre. Hence adequate anti-HBs antibody titres may not be obtained after a primary course of immunization.

In such persons additional doses of the vaccine may be required.

The vaccine does not prevent infection by Hepatitis A, Hepatitis C, Hepatitis D, Hepatitis E or other pathogens known to infect the liver.

Pregnancy:

Adequate human and animal data on use during pregnancy is not available. Hepatitis B vaccine should be used during pregnancy only when definitely indicated,

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and the possible benefits outweigh the possible risks to the foetus.
However as with all inactivated viral vaccines we don't anticipate any harm to the foetus.

Lactation:

Adequate human and animal data on use during lactation is not available. Caution should be exercised when Hepatitis B vaccine is administered to lactating women.
Patients who develop symptoms suggestive of Hypersensitivity after an injection should not receive further injections of the vaccine.

Interactions with other vaccines

Elovac-B® vaccine can be administered concomitantly with DPT, TT, DT, and OPV, if required.
Elovac-B® vaccine can be given together with Measles-Mumps-Rubella vaccines, Haemophilus influenza B vaccine, Hepatitis A vaccine and BCG vaccine.
Different injections should be given at different sites using separate needles and syringes.

Interchangeability with other Hepatitis B vaccines

Elovac-B® can be used for primary vaccinations as well as for booster doses.
Even if the person has been vaccinated by any other Hepatitis B vaccine, the subsequent vaccination series may be continued using Elovac-B®

PRECAUTIONS

- Caution and care should be exercised in administering the Vaccine to individuals with severe compromised cardiopulmonary status as systemic reaction could pose a significant risk
- As with any injectable vaccine, epinephrine should be available for use in case of anaphylaxis or anaphyiactic reaction.
- The vaccine should be well shaken before use.
- In presence of minor infection Elovac-B® to be used only when clearly needed and the possible advantage outweighs the possible risks.

UNDESIRABLE EFFECTS

Most common undesirable effects:

Injection site: Mind soreness, indurations and erythema.

Uncommon undesirable effects classified by body system:

SYSTEMIC: Fatigue, low-grade fever and malaise.
SKIN AND APPENDAGES: Rash, pruritis and urticaria.
MUSCULOSKELETAL SYSTEM: Arthralgia and myalgia.
DIGESTIVE SYSTEM: Nausea, vomiting, diarrhoea and abdominal pain.
HEPATOBILIARY SYSTEM: Abnormal liver function tests.
NERVOUS SYSTEM: Dizziness and paresthesia.

Extremely rare undesirable effects classified by body system:

SYSTEMIC: Anaphylaxis, serum sickness, angioedema and erythema multiforme.
MUSCULOSKELETAL SYSTEM: Arthritis.
CVS: Syncope and hypotension.
NERVOUS SYSTEM: Neuropathy, neuritis (including Guillain - Barre' syndrome, opticneuritis), encephalitis and meningitis.
RESPIRATORY SYSTEM: Bronchoconstriction like symptoms.
LYMPHOID SYSTEM: Lymphadenopathy.

DOSAGE AND ADMINISTRATION DOSAGE:

- NEONATES AND CHILDREN TILL THE AGE OF 19 YEARS:
  The recommended dose of Elovac-B® is 10mcg of antigen protein in 0.5ml sus pension.
- ADULT OVER THE AGE OF 19 YEARS:
  The recommended dose of Elovac-B® is 20mcg of antigen protein in 1ml sus pension.
- **Elovac-B® SHOULD NEVER BE GIVEN INTRAVENOUSLY.**
- Elovac-B® Should be injected intramuscularly in the anterolateral thigh for neo nates and infants.
- Elovac-B® should be intramuscularly in the deltoid for adults.
- Elovac-B® should be not be administered in the gluteal region as the immune response may be lower.
- Elovac-B® may be administered subcutaneously in patients with severe bleed ing tendencies (e.g. haemophilics).

Preparation for administration:

- Elovac-B® is presented as a ready to use suspension.

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- The vaccine should be shaken well to obtain a homogenous turbid white suspen sion.
- The vaccine should be used as supplied and no dilution is necessary.
- The vaccine should be inspected visually for particulate material or discolouration prior to administration.
- Sterile needle and syringe should be used for withdrawal of vaccine.
- Aseptic techniques should be followed.
- Any vaccine remaining in a single dose vial should be discarded.

Immunization Regimen:

Primary immunization with Elovac-B® consists of three intramuscular doses. The second dose given one month after the first and the third dose administered at least four months after the second dose of Elovac-B®

Immunization Schedule:

1st dose	Given on fixed date
2nd dose	4-10 weeks after the 1st dose
3rd dose	4-20 weeks after the 2nd dose
A booster dose is recommended 12 months after the 1st dose.	
A second booster dose may be required after 8 years in the high risk population if the antibody titre falls below 10 mIU/ml.	

Immunization in special situations

- **Known/presumed exposure to HBV**
  First dose of Elovac-B® vaccine can be administered simultaneously with Hepa titis B immunoglobulin, which however must be given at a separate injection site.
- **Neonates born to HBV carrier Mother**
  First dose of Elovac-B® vaccine can be administered simultaneously with Hepa titis B immunoglobulin, which must be given at separate injection site. The immu nization should start immediately after birth and preferably use 0, 1 and 2 months schedule.
- **Chronic haemodialysis Patients**
  The recommended dosage of Elovac-B® vaccine is 40 mcg (2ml) using a 0,1,2, 6 months vaccination schedule. Anti-HBs surveillance every 3-6 months is war ranted so as to maintain the accepted protective level of 10mIU/ml.

PRESENTATION

Elovac-B® is presented as a sterile ready to use slightly turbid white suspension for intra-muscular administration.
Elovac-B® is marked as:

- 0.5ml and 1ml single dose vial.
- 5.0ml and 10.0ml Multi-dose Vial.

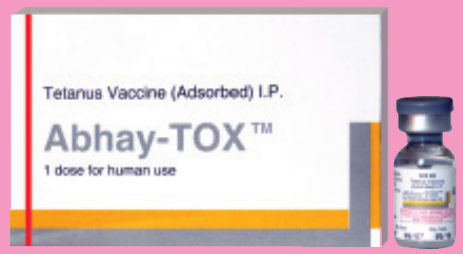
STORAGE:

Protect form light.
DO NOT GREEZE. Discard vial if contents are frozen.
Elovac-B® Must be stored and transported between +2° C & + 8° C.
Elovac-B® Must not be diluted to administer.

For The Use Of Registered Medical Practioner Or Hospital Or Laboratory Only

Abhay-TOX™

Tetanus Vaccine (Adsorbed) I.P.



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DESCRIPTION

Abhay - TOX™ Tetanus Vaccine (Adsorbed) manufactured by Human Biologicals Institute, for intramuscular injection, is a sterile suspension of Aluminium phosphate adsorbed tetanus toxoid in isotonic sodium chloride solution. The vaccine, after shaking, is a turbid liquid, whitish in colour.

COMPOSITION

Each dose of 0.5ml contains:
Active Ingredients:
Tetanus toxoid $\geq$ 5 Lf to $\leq$ 25 Lf
Other ingredients:
Adsorbed on $AlPo_4$ $\geq$ 1.5mg
Thiomersal 0.01% as preservative.

CLINICAL PHARMACOLOGY

Natural immunity to *Clostridium tetani* does not occur. The antigen present in tetanus vaccine is from the formaldehyde treated exotoxin of *Clostridium tetani.*
Following adequate immunization with tetanus vaccine, it is thought that protection persists for at least 10 years.

INDICATIONS AND USAGE

- All Infants 6 to 8 weeks of age or older, all children and all adults should be immu nized against tetanus with the primary series of tetanus vaccine and booster injec tion every 10 years.
- Persons at increased risk of receiving lacerations and abrasions through their occu pation or recreational activities.
- Pregnant woman who are not immunized or inadequately immunized.
- Persons who are injured.

CONTRAINDICATIONS

- Patients with a history of systemic hypersensitivity to toxoids or any of the compo- nents of the vaccine.
- Infants and children with high fever or acute illness.

WARNINGS

- Tetanus vaccine should not be given more frequently than once in every ten years for person with wound who has experienced severe Arthus type hyper sensitivity during the previous dose.
- Pregnant Woman if infected with malaria, the transplacental transfer of antitoxin may be impaired.

Pregnancy: There is extensive human experience in the administration of Tetanus Vaccine products and there is no evidence of teratogenicity.
Lactation: There is no information on the excretion of Tetanus vaccine antigens or antibodies in breast milk during breast-feeding; however, it is unlikely that there is passage of the vaccine.

PRECAUTIONS

An antihistamine may be indicated for mild allergic reactions. For anaphylactic reactions, adrenaline or epinephrine (1 in 1000) may be used.

UNDESIRABLE EFFECTS

Local: Pain at the injection site followed by local redness or swelling and itching at the injection site is common which subsides without treatment.
Systemic: Mild to moderate fever may be observed as systemic undesirable effect in few cases.

DOSAGE AND ADMINISTRATION

Dosage: 0.5ml Intramuscular. From birth to the age of 7 years every child must receive at least 5 doses of a TT containing vaccine. Individuals 7 years of age and older who have not been immunized previously against tetanus, the primary immunization se- ries of Tetanus Vaccine Adsorbed consists of three doses given at intervals of 4 to 8 weeks between the first and second dose and 6 to 12 months between the second and third dose as recommended by Immunization Practices Advisory Committee(ACIP[2])
Preparation For Administration:
Shake the vial to disperse the contents thoroughly immediately before withdrawing

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each dose of vaccine. The vaccine should be administered deep intra-muscularly into the deltoid region. A 24 gauge sterile disposable syringe and needle should be used for each injection.

IMMUNIZATION REGIMEN

Primay Immunization:

Refer under Dosage and administration.

Abhay - TOX™ may be used to complete the primary immunization series for tetanus in children 7 years of age or older who have received one or two doses of whole cell pertussis DTR, DTaP and / or DT vaccine. However the safety and efficacy of Abhay - TOX™ in such children have not been evaluated. Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with Abhay - TOX™. There is no need to start the series over again regardless of the time elapsed between doses.

Pharmaceutical Particulars Incompatibilities

Abhay - TOX™ should not be mixed in the same syringe with any other vaccine.

SHELF LIFE

Three years from the date of manufacture.

PRESENTATION

Abhay - TOX™ vaccine is a sterile, whitish turbid, uniform suspension ready for IM administration.

Abhay - TOX™ is supplied in :

- Single dose rubber stoppered glass vials.
- Multi dose rubber stoppered glass vials.

Special precautions for storage

Protect from light

DO NOT FREEZE Discard vial if contents are frozen. Abhay - TOX™ must be stored and transported between 2°C - 8°C

Instructions for Use and Handling

Shake well before use. Discard if vaccine cannot be re-suspended. Abhay - TOX™ must not be diluted to administer.

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For The Use Of Registered Medical Practioner Or Hospital Or Laboratory Only

Abhay-TAG™ Vaccine

DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE (ADSORBED) I.P.

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DESCRIPTION

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) is a sterile, whitish turbid, uniform suspension of diphtheria, tetanus toxoids and pertussis vaccine adsorbed on Aluminium phosphate and Thiomersal (0.01%) is used as preservative.

COMPOSITION

Each dose of 0.5ml contains
Active ingredients:
Diphtheria toxoid $\geq$ 20 Lf to $\leq$30Lf
Tetanus toxoid $\geq$ 5Lf to $\leq$ 25Lf
B. pertussis $\geq$ 4 IU
Other ingredients:
Adsorbed on Aluminium phosphate ($AlPo_4$) $\geq$ 1.5mg
Thiomersal 0.01%

INDICATIONS AND USAGE

Abhay-TAG™ Vaccine is indicated for the primary immunization of infants, at or above the age of 6 weeks and of children through six years of age against diphtheria, tetanus and whooping cough.
Three intramuscular injection of 0.5ml should be given on 3 separate occasions at 4 weeks interval provide primary immunization for children. The first dose should be started as early as 6 weeks of age. Booster doses should be given 12 months after the primary immunization and also between the ages of 4-6years.

ADMINISTRATION

The vaccine vial should be shaken before use to homogenize the suspension. The vaccine should be injected intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection. A sterile needle and sterile syringe should be used for each injection. It must not be injected into the skin as this may give rise to local reaction.

PRECAUTIONS

For anaphylactic reactions, adrenaline (1:1000) may be used.

WARNINGS

Abhay-TAG™ should be used only for infants and children from 6 weeks through 6 years of age. Persons receiving immunosuppressive drugs may not develop an optimum immune response. Continuous booster doses of tetanus toxoid in the presence of excessive serum levels of tetanus antitoxin is associated with increased incidents of reactions and should be avoided. Tetanus toxoid should be used for booster doses if the hypersensitivity to the diphtheria component is suspected

SIDE EFFECTS

Mild local or systemic reactions are common. Some temporary swelling, tenderness and erythema at the site of injection together with fever occur in a large proportion of cases. Severe reactions of high fever, irritability, drowsiness, persistant or unusual crying symptoms develop within 24 hours of administration occur frequently following injections of this vaccine. Occasionally severe reactions of high fever, collapse and screaming develop within 24 hours of administration. Febrile convulsions have been reported at a rate of one per 12500 doses administered.

CONTRAINDICATIONS

Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) should not be administered to
- Infants or children with high fever or acute illness.
- Presence of neurological disorder.
- Older children (after six years of age) or to adults.
- Child who suffered a severe reaction to the administration of this vaccine earlier.(fever over 40^{0}C, convulsion, screaming episodes and collapse.)

SPECIAL PRECAUTIONS FOR STORAGE

Abhay-TAG™ should be stored and transported between +2^{o}C and +8^{o}C.

IT MUST NOT BE FROZEN

Once opened, multi dose vials should be kept between+2^{o}C and +8^{o}C. Multi dose vials of Abhay-TAG™ from which one or more doses of vaccine have been removed

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during an immunization session may be used in subsequent immunization session upto a maximum 4 weeks, provided that all of the following conditions are met.

- The expiry date has not passed.
- The vaccine is stored under appropriate cold chain conditions.
- The vaccine vial septum has not been submerged in water.
- Aseptic technique has been used to withdraw all doses.

PRESENTATION

Abhay-TAG™ is supplied in:

- Single dose rubber stoppered glass vials.
- Multi dose rubber stoppered glass vials.

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