SUMMARY OF PRODUCT CHARACTERISTICS

Elovac-B*TM*

[ATC Code: J07BC01]

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Manufactured by

HUMAN BIOLOGICALS INSTITUTE
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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: **Elovac-B™**

Generic Name: Hepatitis B Vaccine (rDNA) I.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Elovac-B™ [Hepatitis B Vaccine (rDNA)] is a noninfectious recombinant DNA vaccine. It is a sterile, slightly white, turbid 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 physicochemical methods. The purified antigen is adsorbed on to Aluminium hydroxide gel to prepare bulk vaccine. The vaccine does not contain any material of human or animal origin.

Composition:

Paediatric dose:

Each 0.5 ml contains:

Purified HBsAg	10.0 µg
Aluminum hydroxide gel (equivalent to Al^{+++})	0.25 mg
Thiomersal (as preservative)	0.025 mg
Phosphate Buffer	q.s. to 0.5 ml

Adult dose:

Each 1.0 ml contains:

Purified HBsAg	20.0 µg
Aluminum Hydroxide gel (equivalent to Al+++)	0.50 mg
Thiomersal (as preservative)	0.05 mg
Phosphate Buffer	q.s. to 1.0 ml

3. PHARMACEUTICAL FORM

Liquid suspension for intramuscular injection.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

(i) Routine vaccination:

Newborn, infants, children and adolescents.

(ii) Vaccination of defined high-risk populations:

The following are considered as high-risk population:

1. People who have jobs that involves contact with human blood and other body fluids (Health care personnel and Military personnel etc.).
2. Travelers to areas where Hepatitis B is endemic.
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 acute/chronic HBV infection.
10. Infants born to HBV positive mothers.

4.2. Posology and method of administration

Posology:

PRIMARY IMMUNIZATION

For Routine vaccinations:

S. No.	Population	Schedule
1	Newborn and infants	Schedule 1 Birth dose (within 24 hours) Primary 3 doses at 6, 10 and 14 weeks.
		Schedule 2 Primary 3 doses at 0, 1, and 6 months (first dose at an elected date, second dose one month after first dose and the third dose six months after the first dose)
2	Children Adolescents and Adults	Three doses of vaccine: The first 2 doses are given 1 month apart with the third dose 6 months after the first dose.

Immunization in Special situations:

S. No.	Population	Schedule
1	Preterm babies	Schedule 1 Birth dose (within 24 hours) Primary 3 doses at 6, 10 and 14 weeks.
		Schedule 2 Birth dose (within 24 hours) followed by Primary 3 doses starting from 6 weeks of age; The first two doses are given 1 month apart with the third dose six months after the first dose.
2	Neonate born to HBV carrier mother	Birth dose (within 12 hours) along with HBIG but at a separate injection site. Primary 3 doses at 6, 10 and 14 weeks. Each dose 10 µg.
3	Known/ presumed exposure to HBV	4 dose schedule of 0, 1, 2 and 12 months. Concurrent HBIG should be given with the first dose but at a separate injection site.
4	Immunocompromised or chronic haemodialysis individuals	4 dose schedule of 0, 1, 2 and 12 months (Dose 40 µg).

Booster dose:

Booster doses of Hepatitis B vaccine are recommended only in certain circumstances.

Haemodialysis patients: If annual testing for antibody to Hepatitis B surface antigen (anti-HBs) shows a decline to < 10 mIU/ ml a booster dose should be administered.

Other Immunocompromised persons (HIV infected persons, hematopoietic transplant recipients, and persons receiving chemotherapy): The need for booster doses has not been determined. When anti-HBs declines to < 10 mIU/ ml, annual anti-HBs testing and booster doses should be considered for those with an ongoing risk of exposure. For persons with normal immune status who have been vaccinated, booster doses are not recommended.

Administration:

- Elovac-B vaccine should be administered by intramuscular route only.
- The liquid vaccine vial should be gently shaken before use to obtain a homogenous turbid white suspension.
- The vaccine should be inspected visually for particulate material or discoloration prior to administration.
- A sterile syringe and needle must be used for each injection.
- The site of administration must be sterilized by cotton soaked in rectified spirit which should be allowed to evaporate before injection.

- ***Elovac-B vaccine should never be administered intravenously***.
- The vaccine should be administered by intramuscular route in the deltoid region in adults and older children and in the anterolateral aspect of thigh in the younger children.
- Elovac-B vaccine should not be administered in the gluteal region as the immune response may be lower.

4.3. 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 illness.

4.4. Special warnings and precautions for use

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 and an antihistamine for injection should be available for use in case of anaphylaxis or anaphylactic reaction. Other supportive care for management of such emergency should be available nearby.
- The vaccine should be gently shaken well before use.
- Precaution should be taken while administering the Elovac-B™ vaccine by Intramuscular route to people with known /suspected disorder of bleeding.
- In presence of minor infection, Elovac-B™ to be used only when clearly needed and the possible advantage overweighs the possible risks.

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 given vaccine. The immune response may be dependent upon many factors. People with immunodeficiency or those receiving immuno-suppressive therapy or those who received the vaccine on the gluteal region may have an unsatisfactory antibody titer. Adequate anti-HBs antibody titers may not be obtained after a primary course of immunization. In such persons, additional doses of 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.

4.5. Interactions with other medicinal products and other forms of interactions

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

4.6. Fertility, Pregnancy and Lactation

Pregnancy: Adequate human and animal data on use of Hepatitis B vaccines during pregnancy is not available. Hepatitis B vaccine should be used during pregnancy only when definitely indicated, and the possible benefits outweigh the possible risk to fetus. However as with all inactivated viral vaccines, no harm to the foetus is anticipated or reported.

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.

4.7. Effects on ability to drive and use machines

Elovac-B^{TM} vaccine has not been reported to have any influence on the ability to drive and use machines.

4.8. Undesirable effects

Elovac-B^{TM} is generally well tolerated. The following adverse events have been observed in clinical trial:

Local: Mild pain

Systemic: Fever

The following additional adverse events have been documented involving use of similar Hepatitis B vaccines as per published literatures:

Local: soreness induration and erythema.

Systemic: Fatigue, malaise, rash, pruritus, urticaria, arthralgia, myalgia, nausea, vomiting, diarrhoea, dizziness, paresthesia, and abdominal pain.

Laboratory Parameters: Abnormal liver function test.

Extremely Rare:

Allergic/ hypersensitivity reactions including anaphylaxis, serum sickness, angioedema and erythema multiforme, arthritis, syncope, hypotension, neuropathy, neuritis (including Guillain-Barre' syndrome, optic neuritis), encephalitis and meningitis, bronchoconstriction like symptom, lymphadenopathy.

4.9. Overdose

No case of overdose with Elovac-B vaccine has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

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Elovac-B™ generates specific protective immune response against HBsAg. For protection against HBV infection, anti-HBsAg antibody titer should be equal to or more than 10 mIU/ mL 4 weeks after completion of vaccination course with Elovac-B™.

In A Phase III multicenter study, a total of 235 subjects were recruited who were administered 3-doses, one each on day '0', at 1 month and at 2 months. The Geometric mean titres at 1 month, 2 months, and 3 months from day '0' were 3.9 mIU/ml, 43.9 mIU/ml and 610.4 mIU/ml respectively. After third dose all the subjects seroconverted. After 3rd dose, 99% of the subjects were seroprotected. The vaccine was well tolerated by the subjects. The adverse events reported during the study were pain at the site of inoculation and fever. No serious adverse event was reported during the study period.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Preclinical toxicology study of Elovac-B™ concluded that the vaccine is safe for use at the recommended human dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Aluminum hydroxide gel
Thiomersal
Phosphate Buffer

6.2. Incompatibilities

Elovac-B™ vaccine must not be mixed with Hepatitis-B Immunoglobulin, other vaccine(s) or any other medicinal product(s) in the same syringe.

6.3. Shelf life

Three years from the date of manufacture (when stored at recommended storage conditions including temperature).

6.4. Special precautions for storage

- Protect from light
- Do not freeze
- Discard vial if contents are frozen
- Store out of reach of children.
- Elovac-B^{TM} must be stored and transported between $+2^0$ C and $+8^0$C.
- For Multi-dose vials it has to be ensured that:
    - Expiry date has not passed.
    - The vaccines are stored under appropriate cold chain conditions.
    - The vaccine vial septum has not been submerged in water.
    - Aseptic techniques have been used to withdraw all doses.
    - The vaccine vial monitor (VVM), if present, has not reached the discard point.

6.5. Nature and contents of container

- Combo pack contains single dose of 0.5 ml /1.0 ml of Elovac-B^{TM}, sterile disposable syringe with needle and alcohol swab.
- 0.5 ml and 1.0 ml Single-dose vial.
- 5.0 ml and 10 ml Multi-dose vial.

6.6. Special precautions for disposal and other handling

(A) Disposal:

As per the applicable Biomedical Waste Disposal guidelines/ rule.

(B) Other Handling:

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

7. MARKETING AUTHORISATION HOLDER

Human Biologicals Institute
(A Division of Indian Immunologicals Limited)
Rakshapuram, Gachibowli Post,
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Web: www.indimmune.com

8. MARKETING AUTHORISATION NUMBER

The Marketing Authorization Number is country specific. In India, the country of origin, the Marketing Authorization Number is: 02/RR/AP/2005/V/R.

9. DATE OF FIRST AUTHORISATION

Date of First Authorization in India, the country of origin: 26.04.2006.

10. DATE OF COMPILATION OF THE TEXT

December 2023