1. NAME OF THE MEDICINAL PRODUCT

Name of Medicinal Product:	Hepatitis B Vaccine (rDNA) BP (Paediatric and Adults)
Trade Name:	BEVAC®
Presentation:	0.5 mL - 1 Paediatric dose 1 mL - 1 Adult dose 5 mL - 10 Paediatric doses 10mL - 10 Adult doses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Adult use:

Each dose of 1 mL contains:

Purified HBsAg: 20 µg

Aluminium Hydroxide gel equivalent to Al^{+++}: 0.50 mg

Preservative: Thiomersal B.P.: 0.05 mg

Recombinant HBs Antigen produced in *Pichia pastoris* (Yeast)

Paediatric use

Each dose of 0.5 mL contains:

Purified HBsAg: 10 µg

Aluminium Hydroxide gel equivalent to Al^{+++}: 0.25 mg

Preservative: Thiomersal B.P.: 0.025 mg

Recombinant HBs Antigen produced in *Pichia pastoris* (Yeast)

3. PHARMACEUTICAL FORM

Suspension for Intramuscular Injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

BEVAC® is indicated for active immunization against infection caused by hepatitis B virus and its common sub-types. It can also be given to hepatitis C and D virus infected patients to protect them against co-infection with hepatitis B virus.

BEVAC® is recommended primarily for neonates, infants and young adults not only for the prevention of the disease but also to protect them from probable hepatitis B virus – induced carrier state, cirrhosis and hepato-cellular carcinoma. In addition, for various groups of individuals as listed below, BEVAC® immunization is an essential requirement:

· Healthcare personnel.
· Patients prone to infection due to unscreened or improperly tested blood transfusions.
· Hemophiliacs and patients on haemodialysis.
· Travelers to specified high endemic areas.
· Residents in high endemic areas.
· Persons in contact with infected sexual partners.
· Drug addicts.
· Personnel and residents of community homes and hostels.
· Household contacts of persons with acute or chronic hepatitis B virus infection.
· Infants born to hepatitis B virus carrier mothers.
· Organ transplant receivers.
· Others: Police, Armed forces and such other regimented personnel.

4.2 Posology and method of administration:

Posology

Schedule for infants:

The primary schedule consists of three doses either at 6, 10 & 14 weeks or at birth, 6 & 14 weeks.

Schedule for preterm infants:

The primary schedule consists of four doses at birth, 6, 10 & 14 weeks or at birth, 6 & 14 weeks.

Schedule for older children and adults:

For older children and adults, the preferred schedule is 0, 1 and 6 months, 0 being the elected date for first dose.

Method of administration

The liquid vaccine vial should be shaken before use to homogenize the suspension. BEVAC® should be injected deep intramuscularly into the deltoid muscle region in adults and in the antero-lateral aspect of the upper/mid-thigh in neonates, infants and young children. BEVAC® should not be injected into the gluteal muscles. It is not recommended for intradermal administration.

These routes of administration may result in lower immune response. Under no circumstances BEVAC® should be given intravenously.

4.3 Contraindications:

BEVAC® is generally well tolerated. However, the vaccine should not be administered or repeated to persons known to be hypersensitive to any of the components of the vaccine. Avoid immunization during severe febrile illness.

4.4 Special Warnings and Precautions for use:

Precautions

It is suggested that the medical practitioners ascertain the pre-immunization hypersensitivity status of the subject. In general, biologicals are known to cause reactions occasionally. Sympathomimetic drug like adrenalin may be kept readily available in case of rare anaphylactic reactions due to the vaccine. While using the multi-dose vial, care must be taken to use separate sterile syringe and needle for the administration of every dose.

Before use, BEVAC® should be well shaken to obtain a uniform, whitish translucent suspension. Vaccine should be visually checked for the presence of any particulate matter or other colouration, if any, prior to its administration. If in doubt, do not use the contents of the vial.

NOTE: Because of the long incubation for hepatitis-B virus to manifest the symptoms, some subjects may receive the vaccine while the infection stays unrecognized. In such cases, the ® vaccine may not prevent the onset of hepatitis due to hepatitis - B virus. BEVAC will not prevent hepatitis caused by other viruses such as hepatitis A, hepatitis C and hepatitis D and other agents known to infect the liver.

4.5 Interaction with other medicinal products and other forms of interaction:

Hepatitis B vaccine can be administered safely and effectively at the same time as BCG, DTP, measles, polio (OPV or IPV), *Haemophilus influenzae* type b, or yellow fever vaccines that are extensively used in the Expanded Programme on Immunization (EPI), worldwide or vitamin A supplementation. If hepatitis B vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccine unless it is licensed for use as a combined product (e.g., DTP Hep B/ DTP Hep B-Hib).

4.6 Pregnancy and Lactation:

Routine vaccination of pregnant women with recombinant hepatitis-B vaccine is not recommended due to inadequate data on its effects on the foetus.

No contraindication was recorded for the use of the vaccine in lactating mothers. However, the decision to immunize pregnant and lactating mothers may be taken by the physician in the context of case-specific high-risk factors.

4.7 Effects on ability to drive and use machines:

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable Effects:

BEVAC has proven for low reactogenicity and is well tolerated. Open 3 and comparative trials did not show adverse reactions in the vaccinees. Soreness at the site of injection or a febrile reaction may be observed in some subjects. In rare cases of post vaccinal hypersensitivity, the common symptoms that are quickly recognized by the physician are: dizziness, headache, nausea, abdominal pain, rash, pruritus, urticaria, arthralgia, myalgias and similar associated symptoms and side effects.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

This section is not applicable for this product

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines

5.3 Preclinical safety data

A 14-day acute toxicity study (Single dose toxicity study) and 60 day chronic toxicity study (Repeat dose toxicity study) were conducted on

Hepatitis B Vaccine (rDNA) in mice and rabbits. The objective of the study was to evaluate the potential toxicity of a single dose and repeated doses of Hepatitis B vaccine when administered intramuscularly to mice and rabbits.

The study results revealed that that Hepatitis B vaccine is safe during the single and repeat dose toxicity studies in mice and rabbits.

6. Pharmaceutical Particulars:

6.1 List of Excipients:

Aluminium Hydroxide

Thiomersal (Preservative)

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life:

36 months from the date of manufacture.

6.4 Special precaution for storage:

Store between 2°C to 8°C. Do not freeze. Discard if the vaccine has been frozen. Shake well before use.

6.5 Nature and contents of the container

0.5 mL - 1 Paediatric dose

1 mL - 1 Adult dose

5 mL - 10 Paediatric doses

10mL - 10 Adult doses

7. MARKETING AUTHORISATION HOLDER

Plot No. 1, Biotech Park, Phase-II,
Kolthur Village, Shameerpet,
Medchal-Malkajgiri District,
Telangana State, INDIA - 500078

Registered Office: Biological E. Limited
18/1&3, Azamabad, Hyderabad – 500020, INDIA.

8. MARKETING AUTHORISATION NUMBER(S)

H2015/CTD4020/553

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

3RD DECEMBER 2015

10. DATE OF REVISION OF THE TEXT

May 2026