1. NAME OF THE MEDICINAL PRODUCT

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

Trade Name: BEVAC

Presentation:

For Paediatrics: Single dose vial of 0.5 mL, Two dose vial of 1 mL, Five dose vial of 2.5 mL and Ten dose vial of 5 mL

For Adults: Single dose vial of 1 mL and Ten dose vial of 10 mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Paediatric Dose	**Adult Dose**
	0.5mL	**1.0mL**
Purified HBsAg	≥ 10 µg	≥ 20 µg
Aluminium hydroxide gel equivalent to Al^{+++}	0.25 mg	0.50 mg
Preservative: Thiomersal I.P.	0.025 mg	0.05 mg

3. PHARMACEUTICAL FORM

Hepatitis B Vaccine (rDNA) Suspension for intramuscular injection

White and translucent suspension

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Hepatitis-B vaccine (rDNA) is indicated for prevention of Hepatitis-B infections

4.2. Posology and method of administration

Posology

As indicated in the composition an adult dose is formulated for adults and children above 10 years of age. Paediatric dose is recommended for neonates, infants and children at and below 10 years of age.

- **Primary immunization schedule:**

Age	Schedule – 1 (IAP & WHO)	Schedule – 2 (IAP & WHO)	Schedule – 3 (IAP)
Birth	NA*	1st dose**	At Birth – 1st dose**
6 Weeks	1st dose	2nd dose	1 Month – 2nd dose
10 Weeks	2nd dose	NA	6 Months – 3rd dose
14 Weeks	3rd dose	3rd dose	------
Booster	Booster doses are not recommended.		

*NA – Not Applicable

**Monovalent Hepatitis B vaccine MUST BE USED for the birth dose.

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In order to prevent HBV transmission from mother to infant, the first dose of hepatitis B vaccine needs to be given as soon as possible after birth (preferably within 24 hours). This must be followed by a second and third dose at the time of the first and third diphtheria-tetanus-pertussis (DTP) vaccination.

- **Schedule for Preterm infants:**

Age	Alternate Schedule (WHO) (For Preterm infants with < 2000g Birth weight)
Birth	1st dose**
6 weeks	2nd dose
10 weeks	3rd dose
14 weeks	4th dose

**Monovalent Hepatitis B vaccine MUST BE USED for the birth dose.

- **Schedule for older children and adults:**

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

- **Immunization in special situation:**

- **Immunocompromised Individuals**

  It is recommended that adults with HIV infection receive Hepatitis B vaccination (3doses)

- **Unresponsive Individuals**

  Persons unresponsive to the primary series of hepatitis B (serum anti-HBsAg concentration less than 10 ml U/L), may require revaccination of a fourth or fifth dose, or a new complete course of immunization at the discretion of the medical practitioner.

Method of administration:

Hepatitis B vaccine (rDNA) IP should be injected deep intramuscularly into the deltoid muscle region of the upper arm in adults and in the antero-lateral aspect of the mid/upper thigh in neonates, infants and young children.

4.3. Contraindications

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 practitioner ascertain the pre-immunization hypersensitivity status of the subject. Sympathomimetic drug like Adrenaline 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 vaccine should be well shaken to obtain 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.

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

Hepatitis B vaccine (rDNA) IP has proven for low reactogenicity and is well tolerated. 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.

4.9. Overdose

No Overages added for this product.

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

During the course of 14 day acute toxicity study of recombinant Hepatitis-B vaccine in mice & rabbits, there were no abnormalities observed in the control and treated group animals during the entire period of the study. None of the animals died the study period. No signs of toxicity related to general behavior, central and autonomic nervous, respiratory and circulatory systems were observed in the animals. No signs of erythema or redness or inflammation were observed at the site of injection.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aluminium hydroxide gel equivalent to Al^{+++}

Thiomersal I.P.

6.2. Incompatibilities

In the absence of compatibility studies, BEVAC® must not be mixed with other medicinal products. However, 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).

6.3. Shelf life

36 months from the date of manufacture.

6.4. Special precautions for storage

The vaccine should be stored at a temperature between +2°C to +8°C. Discard if the vaccine has been frozen. Shake well before use.

6.5. Nature and contents of container

The vaccine is filled in USP Type I glass vials closed bromobutyl rubber stoppers and sealed with aluminium flip-off seals. The vaccine is offered in following presentations.

For Paediatrics: Single dose vial of 0.5 mL, Two dose vial of 1 mL, Five dose vial of 2.5 mL and Ten dose vial of 5 mL

For Adults: Single dose vial of 1 mL and Ten dose vial of 10 mL

6.6. Special precautions for disposal

Discard if the vaccine has been frozen as per the approved procedures.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

MF-197/2013

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

05/09/2013

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

Date: 09/2016

BIOLOGICAL E. LIMITED
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