SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Product Name: Hepatitis B Vaccine (r DNA) IP

Brand Name: EnivacHB®

Strength: One pediatric dose is 0.5 ml

Pharmaceutical Form: Injectable Vaccine

EnivacHB® Vaccine (rDNA) is sterile, opaque, uniform suspension of Hepatitis B surface antigen adsorbed on Aluminum hydroxide to which thiomersal is added as a preservative. Surface antigen of the Hepatitis B Virus (HBV) is obtained from cultures of transformed yeast by the insertion in its genome of the gene coding for the surface antigen (HBsAg) using recombinant DNA procedures. The production process of Enivac HB® vaccine complies with WHO recommendations.

The final product has the appearance of a white or almost white suspension which may sediments at the bottom of the container on storage separating into two phases: a clear supernatant essentially protein-free composed of phosphate buffered saline (PBS) with the preservative substance dissolved in it and aluminium hydroxide gel with adsorbed antigen. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product is to be administered.

2. INTERNATIONAL NON PROPRIETARY NAME

Vaccinum Hepatitidis b Recombinatum

3. CHEMICAL NAME

Not Applicable

4. EMPERICAL FORMULA

Not Applicable

5. MOLECULAR WEIGHT

Not Applicable

6. PHARMACOTHERAPEUTIC GROUP

Enivac HB® vaccine belongs to prophylactic group.

7. QUALITATIVE AND QUANTITAVE COMPOSITION

The composition per ml of vaccine is as follows:

Components	Quantity
Purified Surface Antigen (HBsAg)	20 mcg
Aluminium content (Al^{+++}) (As Aluminium hydroxide gel) IP	0.50 mg
Thiomersal IP	0.05mg
Phosphate Buffer Saline	qs

8. PHARMACEUTICAL FORM

Suspension for Intramuscular Injection.

9. CLINICAL PARTICULARS

9.1 Indications:

EnivacHB® Vaccine is indicated for active immunization against Hepatitis B virus.

9.2 Dosage and Administration:

Dosage:

There are multiple options for administration of the hepatitis B vaccine and guidelines of the national immunization programme should be consulted. The choice of schedule should depend on national policy which is based on the local epidemiological situation and programmatic considerations. The minimum

recommended interval between the doses is four weeks. Longer dose intervals may increase the final anti-HBs titres but not the seroconversion rates. More than 3 doses of the vaccine are not required, regardless of duration (> 4 weeks) of the interval between them.

Recommended schedules for vaccination can be divided into those that include a birth-dose and those that do not. Schedules with a birth-dose call for the first vaccination at birth (within 24 hours), followed by a second and third dose at the time of first and third dose diphtheria - tetanus-pertussis (DTP) vaccination, respectively. Alternatively, a four – dose schedule may be used where the dose at birth is followed by three additional doses; these doses may be given either as Monovalent vaccine or as combination e.g. with DTP and/or Hib) following the schedules commonly used for those vaccines. These schedules will prevent most perinatally acquired infection.

Administration:

The liquid vaccine vial should be shaken before use to homogenize the suspension. It should be injected intramuscularly into anterolateral aspect of thigh in infants, or into the deltoid muscles of older children or adults. An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended. A sterile syringe and sterile needle must be used for each injection.

9. 3 Contra-indications

Known hypersensitivity to any component of the vaccine, or a serve reaction to a previous dose. The vaccine will not harm individuals currently or previously infected with hepatitis B virus.

Immuno deficiency
Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with hepatitis B vaccine according to standard schedules.

9.4 Warnings and Precautions:

EnivacHB® vaccine must be stored between +2°C and +8°C. It must not be frozen

9.5 Interactions:

EnivacHB® vaccine can be given safely and effectively at the same time as BCG, DTP, Measles, polio (OPV or IPV), *Haemophilus influenzae* type b, or yellow fever vaccines or vitamin A supplementation. If EnivacHB® vaccine is given at the same time as other vaccines, it should be administered at separate site. It should not be a mixed in the vial or syringe with any other vaccine unless it is licensed for use as combination product (e.g DTP-Hep B/DTPHepHib)

9.6 Adverse reactions:

The vaccine is very well tolerated. In placebo-controlled studies, with exception of local pain, reported events such as myalgia and transient fever have not been more frequent than in the placebo group. Reports of severe analphylactic reactions are very rare. Available data do not indicate a casual association between hepatitis B vaccine and Guillain-Barre syndrome, or demyelinating disorders including multiple sclerosis, nor is there any epidemiological data to support a causal association between hepatitis B vaccination and chronic fatigue syndrome, arthritis, autoimmune disorders, astma, sudden infant death syndrome, or diabetes.

9.7 Overdosage and Treatment:

Not Applicable, as EnivacHB® vaccine is to be administered as per the pediatric immunization schedule under the direct supervision of physicians.

10. PHARMACOLOGICAL INFORMATION

10.1 Pharmacodynamic properties

In the clinical study the EnivacHB® vaccine has been found to be safe & highly immunogenic. The vaccine showed sero-protection rate (antiHBs ≥ 1mIU/ml) in 97.87% of the subjects

10.2 Pharmacokinetic profile

Not Applicable.

11. PHARMACEUTICAL INFORMATION

11.1 Shelf life

36 months from the date of manufacturing, when stored at 5°C ± 3°C.

11.2 Precautions for Storage

EnivacHB® vaccine must be stored between +2°C and +8°C. It must not be frozen. Multi dose vials of hepatitis B vaccine from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for up to maximum of 4 weeks.

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

11.3 Nature and contents of the container

EnivacHB® vaccine is to be filled in tubular, colorless glass vials and stoppered with bromo butyl rubber closures and finally sealed with flip off aluminium seals as well as in Pre-filled syringe of USP type 1 glass stoppered with plunger stopper in below mentioned presentations:

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Vial Presentations:

Pediatric:
Single dose vial containing 0.5 ml vaccine.
Multi-dose vial containing 2.5 ml vaccine
Ten paediatric doses vial containing 5.0 ml vaccine

Adult:
Single dose vial containing 1.0 ml vaccine
Ten doses vial containing 10.0 ml vaccine

Prefilled Syringe Presentations:

Pediatric:
Single dose Prefilled Syringe containing 0.5 ml vaccine.

Adult:
Single dose Prefilled Syringe containing 1.0 ml vaccine.

12. MARKETING AUTHORIZATION HOLDER

Panacea Biotec Ltd.
Malpur, Baddi, Distt Solan,
Himachal Pradesh – 173205, India
Tel. : 01795-674036
E-mail : corporate@panaceabiotec.com
Website: https://www.panaceabiotec.com

13. MARKETING AUTHORIZATION NUMBER

License No. : MB/07/632

14. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The details of the manufacturing authorization certificates obtained from Licensing Authority, India for EnivacHB vaccine manufactured at Vaccine Formulation Plant (VFP), Baddi, Himachal Pradesh, India are as mentioned below:

- Date of first authorization: September 29, 2007
- Renewal of the authorization: granted on September 29, 2012 valid up to 28.09.2017
- Renewal of the authorization: granted on September 29, 2017 valid up to 28.09.2022
- Retained up to September 28, 2027