1. NAME OF THE MEDICINAL PRODUCT AND STRENGTH

1.1 Brand Name : Hepavax-B Injection
1.2 Generic Name : Hepatitis B Vaccine (rDNA)
1.3 Strength : Hepatitis B Virus surface antigen NLT 20 µg /ml

Presentation:

For Pediatrics **:** Single dose vial of 0.5 ml
For Adults **:** Single dose vial of 1.0 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Each dose of 0.5 ml & 1.0 ml contains:

Composition	Pediatric Dose 0.5 ml	Adult Dose 1.0 ml
Recombinant Hepatitis B surface antigen (HBsAg)	10.000 µg	20.000 µg
Aluminium (Al3+) (As Aluminium Hydroxide Gel)	0.250 mg	0.500 mg
Thiomersal	0.025 mg	0.05 mg
Water for Injections	q.s. to 0.5 ml	q.s. to 1.0 ml

3. PHARMACEUTICAL FORM

Hepavax-B Vaccine (rDNA) sterile suspension for intramuscular injection white and translucent suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hepavax-B is indicated for active immunization against infection caused by all known subtypes of Hepatitis B virus.

4.2 Posology and Method of Administration

4.2.1 Posology

As Indicated in the composition an adult dose is formulated for adults and children above 10 years of age. Pediatric dose recommended for neonates and children at and below 10 years of age.

4.2.1.1 **Primary vaccination:**

Primary immunization with Hepavax-B consists of three intramuscular doses. The second dose given one month after the first and the third dose administered at least four month after the second dose of Hepavax-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 titer falls 10 mIU/ml	

4.2.2 **Pediatric Population**

4.2.2.1 All infants should receive their first dose of Hepatitis b vaccine as soon as possible after birth, preferably within 24 hours.

4.2.2.2 The birth dose should be followed by two or three doses to complete the primary series.

4.2.3 **Method of Administration**

The liquid vaccine vial should be shaken before use to homogenize the suspension. It should be injected intramuscularly into the anterolateral aspect of the 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.

4.3 Contraindications

4.3.1 **HEPAVAX-B** should not be administered to any person who has experienced a hypersensitivity reaction to any component of any Hepatitis B recombinant DNA vaccine. HEPAVAX-B should not be administered to subjects with pyrexia or have severe febrile infections.

4.4 Special warnings and precaution for use

4.4.1 HEPAVAX-B should never be given intravenously.

4.4.2 HEPAVAX-B should be injected intramuscularly in the anterolateral thigh for neonates and infants.

4.4.3 HEPAVAX-B should be given intramuscularly in the deltoid for adults.

4.4.4 HEPAVAX-B should not be administered in the gluteal region as the immune response may be lower.

4.4.5 HEPAVAX-B may be administered subcutaneously in patients with severe bleeding tendencies (e.g. hemophiliacs)

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

4.5.1 HEPAVAX-B vaccine can be administered concomitantly with DTP, BCG, Measles, polio (OPV/IPV), Haemophilus influenzae type b, or yellow fever vaccines or vitamin A supplementation. If hepatitis B 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/DTP-Hep-Hib).

4.6 Fertility, Pregnancy and Lactation

On the basis of limited experiences, there is no apparent risk of adverse effects of developing fetuses when hepatitis b vaccine is administered to pregnant women. Neither pregnancy nor lactation should be considered a contraindication to vaccination of women.

4.7 Effects on Ability to Drive and Use Machines

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

4.8 Undesirable Effects

4.8.1 Injection site: Mild soreness, indurations and erythema.

4.8.2 Uncommon undesirable effects classified by body system:
- 4.8.2.1 Systemic: Fatigue, low-grade fever and malaise.
- 4.8.2.2 Skin and Appendages: Rash, pruritus and urticaria.
- 4.8.2.3 Musculoskeletal System: Arthralgia and myalgia.
- 4.8.2.4 Digestive System: Nausea, vomiting, diarrhea and abdominal pain.
- 4.8.2.5 Hepatobiliary System: Abnormal liver function tests.
- 4.8.2.6 Nervous System: Dizziness and paresthesia.

4.9 Overdose
No case of overdose has been reported.

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 vaccine.

5.3 Preclinical safety Data
5.3.1 During the course of 14 day acute toxicity study of recombinant Hepatitis-B vaccine in mice and rabbits, there were no abnormalities observed in the control and treated group animals during the entire period of 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
- 6.1.1 Aluminium (Al+3) (As Aluminium Hydroxide Gel)
- 6.1.2 Thiomersal
- 6.1.3 Water for Injections

6.2 Incompatibilities
6.2.1 In the absence of compatibility studies, Hepavax-B must not be mixed with other medicinal products.

6.3 Shelf Life
3 years from the manufacturing Date of Ready to Fill (RTF) Bulk.

6.4 Special precautions for storage
- 6.4.1 Keep out of the reach and sight of children.
- 6.4.2 Store and transport at 2 ºC to 8 ºC.
- 6.4.3 Do not freeze. Discard vaccine if frozen.
- 6.4.4 Protect from light.
- 6.4.5 Shake well before use.

6.5 **Nature and contents of container and special equipment for use,administration or implantation**

The vaccine is filled in USP Type I glass vials closed bromobutyl rubber stoppers and sealed with aluminium flip-off seal along with 2ml sterile disposable syringe with needle into a plastic tray.

For Pediatrics : Single dose vial of 0.5 ml along with sterile disposable syringe with needle into a plastic tray.

For Adults : Single dose vial of 1.0 ml along with sterile disposable syringe with needle into a plastic tray.

6.6 **Special precautions for disposal and other handling**

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

6.6.2 The vaccine should be inspected visually in order to detect any appearance of precipitate or discoloring of the content prior to administration. If these conditions exist, the product should not be administered.

6.6.3 Before use, the vial should be well shaken.

6.6.4 Once the vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

6.6.5 Any unused vaccine product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER NAME AND ADDRESS

Head Office Address:

Popular Pharmaceuticals Ltd.
Sheltech Panthokunjo, 17 Shukrabad, West Panthopath, Dhaka - 1207, Bangladesh
Email: info@popularbd.com
Phone: +880-2-9101730-2, +880-2-9102850-3
Fax: +880-2-9134054, +880-2-9134096
Mobile: +880-1833332352-55

Factory Address:

Popular Pharmaceuticals Ltd.
164, Tongi Industrial Area, Monnunagar,
Gazipur – 1710, Bangladesh
Email: info@popularbd.com
Phone: +880-2-9812971-5
Fax: +880-2-9812976

8. DRUG AUTHORIZATION NUMBER

MA No.: 336 – 473 – 069 (For child)
MA No.: 336 – 551 – 069 (For Adult)

9. DATE OF FIRST AUTHORIZATION

Child dose annexure:

Date of First Authorization : 20.02.2011
Date of Latest Renewal : 10.05.2022

Adult dose annexure:

Date of First Authorization : 23.12.2012
Date of Latest Renewal : 10.05.2022

10. DATE OF REVISION OF THE TEXT

08.08.2023