Hepa-B®

Hepatitis B Vaccine (rDNA) BP

Presentation
Hepa-B® for pediatric: Each vial contains 0.5 ml Hepatitis B Vaccine (rDNA) BP containing ≥10 µg of Hepatitis B surface antigen adsorbed on Aluminium Hydroxide gel equivalent to Al^{3+} 0.25 mg. Thiomersal 0.025 mg as preservative.
Hepa-B® for adult: Each vial contains 1 ml Hepatitis B Vaccine (rDNA) BP containing ≥20 µg of Hepatitis B surface antigen adsorbed on Aluminium Hydroxide gel equivalent to Al^{3+} 0.5 mg. Thiomersal 0.05 mg as preservative.

Description
Hepa-B is a noninfectious recombinant DNA Hepatitis B vaccine. It is sterile suspension of purified surface antigen of hepatitis B virus obtained by culturing genetically engineered yeast cells of *Pichia pastoris*, which carry the gene that codes for the HBsAg. The HBsAg protein expressed in *Pichia pastoris* cells is purified by several physicochemical steps and formulated as a suspension of the antigen adsorbed on aluminium hydroxide. No substances of human origin are used in its manufacture.

Indications and uses
Hepa-B is indicated for active immunization against infection caused by all known subtypes of Hepatitis B virus. As Hepatitis D (caused by the delta virus) does not occur in the absence of Hepatitis B infection, it can be expected that Hepatitis D will also be prevented by Hepatitis B vaccination.

Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to Hepatitis B virus, for example:

- A baby whose mother is infected can be infected at birth
- Children, adolescents, and adults can become infected by:
  - Contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores
  - Contact with objects that have blood or body fluids on them such as toothbrushes, razors or monitoring and treatment devices for diabetes
  - Having unprotected sex with an infected person
  - Sharing needles when injecting drugs
  - Being stuck with a used needle
  - Household contacts of people infected with Hepatitis B
  - Residents and staff in institutions for the developmentally disabled
  - Kidney dialysis patients
  - People who travel to countries where Hepatitis B is common
  - People with HIV infection
  - Persons with hemophilia, thalassemia, sickle cell anemia, cirrhosis
- Military personnel identified as being at increased risk
- Morticians and Embalmers
- Prisoners
- Users of illicit injectable drugs
- Others: Police, fire department personnel, who render first aid or medical assistance, and any others who, through their work or personal life-style, may be exposed to the Hepatitis B virus.

Dosage and administration
Neonates, infants and children upto 19 years of age: The recommended dose of Hepatitis B vaccine (rDNA) is ≥10 µg of antigen protein in 0.5 ml.

Adults 19 years of age and older: The recommended dose of Hepatitis B vaccine (rDNA) is ≥20 µg of antigen protein in 1 ml.

Primary immunization schedule for all ages:

The usual immunization schedule consists of 3 doses of vaccine-

- First dose: at elected date
- Second dose: 1 month after first dose
- Third dose: 6 months after first dose

or

Accelerated schedule consists of 4 doses of vaccine-

- First dose: at elected date
- Second dose: 1 month after first dose
- Third dose: 2 months after first dose
- Fourth dose: 12 months after first dose

Accelerated schedule confer protection more quickly and is expected to provide better patient compliance.

Neonate born to hepatitis B surface antigen-positive mother, 4 doses of 10 micrograms:

- First dose: at birth with Hepatitis B immunoglobulin injection (separate site)
- Second dose: 1 month after first dose
- Third dose: 2 months after first dose
- Fourth dose: 12 months after first dose

For travellers departing within 1 month, adult over 18 years-

- First dose: at elected date
- Second dose: 7 days after first dose
- Third dose: 21 days after first dose
- Fourth dose: 12 months after first dose

Renal insufficiency (including haemodialysis patients), adult and child over 16 years 4 doses of 40 micrograms-

- First dose: at appropriate date
- Second dose: 1 month after first dose
- Third dose: 2 months after first dose
- Fourth dose: 6 months after first dose

Immunization schedule and booster doses may need to be adjusted in those with low antibody concentration.

Booster vaccinations:
For persons with normal immune status who have been vaccinated, booster doses of Hepatitis B vaccine has not been established. However, booster doses are recommended for hemodialysis patients or other immunocompromised persons.

Method of administration
Hepa-B is for intramuscular injection only. Do not inject intravenously.
Hepa-B should be given intramuscularly in the deltoid muscle of adult and children or in the anterolateral aspect of thigh in children under 1 year.

Preparation for administration

- The vaccine should be shaken well before use to obtain a homogenous turbid white suspension. Do not shake vigorously.
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The vaccine should be used as supplied; no dilution is necessary.

Contra-indications
Hypersensitivity to any component of the vaccine, including yeast, is a contraindication. This vaccine is contraindicated in patients with previous hypersensitivity to any Hepatitis B virus containing vaccine.

Co-administration
Hepatitis B vaccine can be given at the same time with other vaccine as Diphtheria, Tetanus, Pertussis (DTP), Polio (OPV), Measles, Mumps and Rubella (MMR), *Haemophilus influenzae* b, Hepatitis A and BCG vaccines at separate sites and with separate syringes. It should not be mixed with other vaccines or medicinal products in the same syringe.

Pregnancy and Lactation

Pregnancy: The effect of Hepatitis B on fetal development or reproduction capacity has not been evaluated. However, it should only be used during pregnancy when there is a high risk of infection.

Lactation: Adequate human data on use during lactation and adequate animal reproduction studies are not available. It may be administered to nursing mothers only if clearly needed.

Side effects
Hepatitis B vaccine is generally well tolerated. Most recipients of Hepatitis B vaccine experience some reactions upon vaccination. These are generally moderate and short. They mainly consist of local reactions at the injection site (erythema, induration and tenderness). Systemic reactions (malaise, headache, diarrhea, vomiting, myalgia and elevated temperature) are reported less commonly. In very rare cases allergic type reactions (pruritus, rash, urticaria) may be observed.

Overdose
Not applicable.

Storage

- Keep out of the reach and sight of children
- Store at +2 °C to +8 °C. Transportation should also be at +2 °C to +8 °C
- Protect from light
- Do not freeze

Commercial Pack
Hepa-B® for pediatric: Each box contains 1 vial of 0.5 ml suspension of Hepatitis B Vaccine (rDNA), one sterile disposable syringe and 2 needles.

Hepa-B® for adult: Each box contains 1 vial of 1 ml suspension of Hepatitis B Vaccine (rDNA) and one sterile disposable syringe.

Manufactured by
Incepta Vaccine Ltd
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V.N. 05