**Bio-Hep-B**

**Description**

Bio-Hep B® (Hepatitis B Vaccine [Recombinant]) is a third generation vaccine produced by culture of Chinese hamster ovary cells. It consists of 22 nm particles isolated and purified from culture medium. The particles contain all three epitopes of hepatitis B surface antigen (HBsAg), namely S, pre-S1 and pre-S2, in their glycosylated and non-glycosylated forms, embedded in a phospholipid matrix, thus resembling the authentic plasma HBsAg. The antigen is formulated by adsorption onto aluminum hydroxide. The final preparation is virtually free of DNA and contains less than 3% protein contaminants. It does not contain any known animal viruses, bacteria or Mycoplasma.

Each batch of the vaccine is rigorously tested for purity, safety, sterility and potency.

**Bio-Hep-B** is a sterile suspension for intramuscular injection. It is supplied in four presentations:

- **Adult Formulation**, 10 µg/ml: each 1 ml dose contains 10 µg hepatitis B surface antigen; recommended for children above the age of 10 years and adults.
- **Pediatric Formulation**, 2.5 µg/0.5 ml: each 0.5 ml dose contains 2.5 µg hepatitis B surface antigen recommended for neonates, infants and young children.
- **Pediatric Formulation**, 5 µg/0.5 ml: each 0.5 ml dose contains 5 µg hepatitis B surface antigen recommended for neonates, infants and young children in highly endemic areas.
- **Multidose Formulation**, 50 µg/5 ml: each 1 ml dose contains 10 µg hepatitis B surface antigen; recommended for children above the age of 10 years and adults. Each 0.5 ml dose contains 5 µg hepatitis B surface antigen recommended for neonates, infants and young children in highly endemic areas.

In each formulation, the hepatitis B surface antigen is adsorbed onto approximately 0.5 mg of aluminum per ml of vaccine.

**Indications and Usage**

Bio-Hep-B is indicated for active immunization against hepatitis B virus.

Immunization against hepatitis B is expected, in the long term, to reduce not only the incidence of the disease, but also its chronic complications such as massive hepatic necrosis, cirrhosis of the liver and hepatocellular carcinoma.

Vaccination with Bio-Hep-B is recommended for all ages in those subjects who are or will be at increased risk of infection with hepatitis B virus. In areas of high prevalence of infection, the majority of the population is at high risk, especially neonates and children. In high risk areas, infection occurs primarily through mother-child transmission. Therefore, vaccination should be targeted to prevent such transmission. In areas of low prevalence, vaccination is recommended for neonates, infants and adolescents, as well as subjects who are or will be at increased risk of infection, such as:

- Health care personnel
- Frequent recipients of blood products
- Infants born to HBsAg-positive mothers
- Personal and residents of public health institutions
- Persons at increased risk of the disease due to their sexual practices

Bio-Hep-B is indicated for active immunization against hepatitis B virus. It is generally well tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In a series of studies, 2313 doses of Bio-Hep-B were administered to 771 healthy adults who were monitored for 5 days after each dose. The following adverse reactions were reported:

- **Incidence Equal to or Greater Than 1% of Injections**
  - Fatigue
  - Headache
  - Chills
  - Myalgia
  - Arthralgia
  - Increased transaminases
  - Increased gamma GT
  - Insomnia
  - Irritability

- **Incidence Less Than 1% of Injections**
  - Rash
  - Pruritus
  - Vomiting
  - Diarrhea
  - Nausea
  - Cephalgia

**Adverse Reactions**

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**Dosage and Administration**

Method of Administration: Bio-Hep-B should be injected intramuscularly into the deltoid muscle in adults and children or in the anterolateral thigh in neonates, infants and young children.

The vaccine should be stored in the dark at +2°C to +8°C. Do Not Freeze.

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