Prescription Only

Hepavax-B

rDNA Hepatitis B Vaccine BP

For Intramuscular Injection only

Indicated for active immunization against infection caused by all known subtypes of Hepatitis B Virus

Description

Hepavax-B is a preparation of the surface antigen of the hepatitis B virus (HBV) obtained from cultures of transformed yeast by insertion in its genome the gene coding for the surface antigen using recombinant DNA procedures. The production process of the recombinant Hepatitis B vaccine conforms to WHO's Good Manufacturing Practices (GMP & Good Laboratory Practices (GLP). The expression product of this gene is extracted and purified by a combination of physical, chemical and biochemical procedures. The final product has the appearance of a white or almost white suspension which may sediment 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 more than 98% of the antigen adsorbed. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product should be administered.

Indications and Uses

Hepavax-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
- Health care personnel
- Patients frequently receiving blood products
- Personnel and residents of institutions
- Persons at increased risk due to their sexual behavior
- Illicit users of addictive injectable drugs
- Sharing needles when injecting drugs
- Travelers to areas with a high endemicity of HBV
- Patients with sickle-cell anemia
- Patients who are candidates for organ transplantation
- Household contacts of any of the above groups and of patients with acute or chronic HBV infection
- Subjects with chronic liver disease (CLD) or at risk of developing CLD (e.g. Hepatitis C virus carriers, persons who abuse alcohol)
- Kidney dialysis patients
- Prisoners
- Others: Police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV

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. The pediatric dose is 0.5 ml and adult dose is 1.0 ml. A sterile syringe and sterile needle must be used for each injection.

Routine Vaccination

New born, infants, children and adolescents.

Contraindication

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

Side Effects

Hepatitis B vaccine is well tolerated. Reports of severe anaphylactic reactions are very rare. Available data do not indicate a causal 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, asthma, sudden infant death syndrome, or diabetes.

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.

Drug Interaction

Hepatitis B vaccine can be administered concomitantly with DTP, BCG, Measles, polio (OPV/IPV), Haemophilus influanzae 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).

Undesirable Effects

Most common undesirable effects

Injection site: Mild soreness, indurations and erythema.

Uncommon undesirable effects classified by body system

Systemic: Fatigue, low-grade fever and malaise.
Skin and Appendages: Rash, pruritis and urticaria.
Musculoskeletal System: Arthralgia and myalgia.
Digestive System: Nausea, vomiting, diarrhoea and abdominal pain.
Hepatobiliary System: Abnormal liver function tests.
Nervous System: Dizziness and paresthesia.

Precautions

- Hepatitis B vaccine should never be given intravenously.
- Hepatitis B vaccine should be injected intramuscularly in the anterolateral thigh for neonates and infants.
- Hepatitis B vaccine should be given intramuscularly in the deltoid for adults.
- Hepatitis B vaccin should not be administered in the gluteal region as the immune response may be lower.
- Hepatitis B vaccine may be administered subcutaneously in patients with severe bleeding tendencies (e.g. haemophilics).

Immunization Regimen

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 months 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 below 10 ml U/ml	

Pharmaceutical Precautions

- Keep out of the reach and sight of children
- Store & transport at 2°C to 8°C
- Protect from light
- Do not keep in deep freeze
- Do not diluted to administer

Presentation

Hepavax-B is marked as:

Single dose (0.5 ml) rubber stopper glass vial along with 2 ml sterile disposable syringe with needle for children.

Single dose (1.0 ml) rubber stopper glass vial along with 2 ml sterile disposable syringe with needle for adult.

Manufactured by :

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