CEFVAC-B Vaccine (Hepatitis B Vaccine (rDNA) I.P. (Genetically Engineered))

**Composition**

CEFVAC-B
Each dose of 1 ml contains:-
20 mcg of purified Hepatitis B surface antigen
Adsorbed on Aluminium hydroxide (Al+++ 0.50 mg to 0.80 mg
Thiomersal Free
Produced in Hansenula polymorpha (yeast)

**Dosage Form**

Ampoule for intramuscular injection

**Pharmacology**

**Pharmacodynamics**

CEFVAC-B (Hepatitis - B Vaccine (rDNA) I.P.) is a non-infectious recombinant DNA Hepatitis B Vaccine. It contains purified surface antigen of the virus obtained by culturing genetically-engineered Hansenula polymorpha yeast cells having the surface antigen gene of the Hepatitis B virus. The Hepatitis B surface antigen (HBsAg) expressed in the cells of Hansenula polymorpha is purified through several chemical steps and formulated as a suspension of the antigen adsorbed on aluminium hydroxide. The vaccine does not contain any material of human or animal origin.

**Indications**

CEFVAC-B is indicated for active immunisation against hepatitis B infection in subjects considered at risk of exposure to HBV-positive material. Immunisation against hepatitis B is expected in the long term to reduce not only the incidence of this disease, but also its chronic complications such as chronic active hepatitis B and hepatitis B associated cirrhosis and primary hepatocellular carcinoma.

In areas of low prevalence of hepatitis B, immunisation with CEFVAC-B is recommended for neonates/infants and adolescents as well as for subjects who are, or will be, at increased risk of infection such as:

- Health Care Personnel.
- Patients receiving frequent blood products.
- Personnel and residents of institution.
- Persons at increased risk due to their sexual behavior.
- Illicit users of addictive injectable drugs.
- Travellers to areas with a high endemicity of HBV.
Infants born of mothers who are HBV carries.
Persons originating from areas with a high endemicity of HBV.
Others: Police personnel, fire brigade personnel, armed forces personnel and anybody who through their work or personal lifestyle may be exposed to HBV.
Household contacts of any of the above groups and of patients with acute or chronic HBV infection.

In areas of intermediate or high prevalence of hepatitis B, with most of the population at risk of acquiring the disease, immunisation should be offered to all neonates and young children. Immunisation should also be considered for adolescents and young adults. The vaccine can be safely and effectively given simultaneously but at different injection site with DTP, DT, TT, BCG, Polio vaccine (OPV and IPV), yellow fever vaccine, Haemophilus influenzae type b and vitamin A supplementation.

**Dosage And Administration**

Adult dose vaccine: 20 mcg dose (in 1.0 ml suspension) is recommended for adults aged 20 years and above.

### Preparation for Administration

CEFVAC-B should be injected intramuscularly in the deltoid region in adults and children or in the anterolateral thigh in neonates, infants and young children. The vaccine may be administered subcutaneously in patients with thrombocytopenia or bleeding disorders. The vaccine should be well shaken before use. Only sterile needle and syringes should be used for each injection.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Do not administer this product intravenously or intradermally.

### Recommended Dose and Schedule

**Primary Immunisation.** A series of three intramuscular injections is required to achieve optimal protection.

The following immunisation schedules can be recommended:

- 6, 10, 14 weeks for infants
- 0, 1, 6 months
- 0, 1, 2 months (rapid schedule)

The immunisation schedule should be adapted to meet local immunisation recommendations.

**Booster dose**

The need for the booster dose in healthy individuals who have received the full primary immunization, is not recommended. It would seem advisable to recommend a booster dose when Anti-HBs antibody titres fall below 10 IU/L for all people at risk and especially for patients who are immunocompromised (HIV infected patients) or those on haemodialysis.

### Special Dosage Recommendations

**Dosage recommendation for neonates born of mothers who are HBV carriers**

The 0, 1, 2 month immunisation schedule is recommended, and should start at birth. Concomitant administration of Hepatitis B immunoglobulin not necessary, but when Hepatitis B immunoglobulin is given simultaneously with CEFVAC-B a separate injection site must be chosen.

**Dosage recommendation for known or presumed exposure of HBV**

In circumstances where exposure to HBV has recently occurred (e.g. needles stick with contaminated needle) the first dose of CEFVAC-B can be administered simultaneously with Hepatitis B immunoglobulin which however must be given at
a separate injection site. The rapid immunisation schedule should be advised.

**Dosage recommendation for immunocompromised persons**
The primary immunisation schedule for chronic haemodialysis patients or persons who have an impaired immune system is four doses of 40 mcg at 0, 1, 2 and 6 months from the date of first dose. The immunisation schedule should be adapted in order to ensure that the anti-HBs antibody titre remains above the accepted protective level of 10 IU/L.

**Contraindications**
CEFVAC-B should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after previous Hepatitis B Vaccine administration.

**Warnings And Precautions**
Because of the period of latency of hepatitis B infection it is possible for unrecognised infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases. The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E and other pathogens known to infect the liver. The immune response to Hepatitis B vaccines is related to age. In general, people over 40 years of age respond less well. In haemodialysis patients and persons with an impaired immune system, adequate anti-HBs antibody titres may not be obtained after the primary immunisation course and such patients may therefore require administration of additional doses of vaccine (see Dosage recommendation for Immunocompromised persons).

As with all injectable vaccines, appropriate medication (e.g. adrenaline) should always be readily available for treatment in case of rare anaphylactic reactions following the administration of the vaccine. **ADRENALINE INJECTION (1:1000) MUST BE IMMEDIATELY AVAILABLE SHOULD AN ACUTE ANAPHYLACTIC REACTION OCCUR DUE TO ANY COMPONENT OF THE VACCINE.** For treatment of severe anaphylaxis the initial dose of adrenaline is 0.1 - 0.5 mg (0.1 - 0.5 ml of 1:1000 injection) given s/c or i/m. Single dose should not exceed 1 mg (1 ml). For infants and children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml). The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis.

As with the use of all vaccines, those vaccinated should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

Special care should be taken to ensure that the injection does not enter a blood vessel.

CEFVAC-B should not be administered in the gluteal muscle or intradermally since this may result in a lower immune response.

CEFVAC-B may be used to complete a primary immunisation course started either with plasma-derived or with other genetically-engineered hepatitis B vaccines, or as a booster dose in subjects who have previously received a primary immunisation course with plasma-derived or with other genetically-engineered hepatitis B vaccines.

**Undesirable Effects**
The undesirable events are temporally related to the administration of Hepatitis B Vaccine. They are usually mild and confined to the first few days of the vaccination. The most common reactions are mild soreness, erythema, induration, fatigue, fever, malaise, influenza-like symptoms. Less common systemic reactions include nausea, vomiting, diarrhoea, abdominal pain, abnormal liver function tests, arthralgia, myalgia, rash, pruritus, urticaria, liver function.
Storage And Handling Instructions

CEFVAC-B should be stored between 2° and 8°C. Not to be frozen. Discard if vaccine has been frozen.

Packaging Information

CEFVAC-B: 1 ml.... 1 Dose Ampoule (Adult)
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