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Gene Vac-B®

Recombinant Hepatitis-B Vaccine I.P.

DESCRIPTION

Gene Vac-B™ (Recombinant Hepatitis - B Vaccine, 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 and thiomersal is added as preservative. The vaccine does not contain any material of human or animal origin.

COMPOSITION

Each ml contains :
20 mcg of purified Hepatitis B surface antigen
Adsorbed on Aluminium hydroxide (Al^{+++}) ⩽1.25 mg
Preservative: Thiomersal ⩽0.01%
Produced in Hansenula Polymorpha (yeast)

Dose : 1 Paediatric dose - 0.5 ml
1 Adult dose - 1 ml
By intramuscular injection

INDICATIONS

Gene Vac-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 Gene Vac-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) and yellow fever vaccine.

CONTRAINDICATIONS
Gene Vac-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.

PRECAUTIONS AND WARNINGS
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 haemodiaysis 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 (eg adrenaline) should always be readily available for treatment in case of rare anaphylactic reactions following the administration of the vaccine.

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

Gene Vac-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.

ADVERSE REACTIONS
The undersirable 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 liverfunction tests, arthralgia, mystalgia, rash, pruritus, urticaria, liver function.

DOSAGE AND ADMINISTRATION
Paediatric dose vaccines 10 mcg dose (in 0.5 ml suspension) is recommended for neonates, infants and children upto 10 years of age.
Adult dose vaccine 20 mcg dose (1.0 ml suspension) is recommended for adults and children above 10 years of age.

IMMUNISATION SCHEDULE
Primary Immunisation A series of three intramuscular injections is required to achieve optimal protection.
Two primary immunisation schedules can be recommended:

- A rapid schedule, with immunisation at 0,1 and 2 months, will confer protection more quickly and is expected to provide better patient compliance.
- Schedules which have more time between the second and third doses. such as immunisation at 0,1 and 6 months, may take longer to confer protection, but will produce higher anti-HBs antibody titres.

The immunisation schedule may be adapted to meet local immunisation recommendations.
The following timing of injections gives general guidance :

1st dose	at elected date
2nd dose	4 to 10 weeks after the 1st dose
3rd dose	1 to 5 months after the 2nd dose

BOOSTER DOSE.
It would seem advisable to recommend a booster dose when the anti-HBs antibody titre falls below 10 IU/L, particularly for all people at risk.

- After the 0, 1, 2 month primary immunisation schedule a booster dose is recommended 12 months after the first dose. The next booster may be required after 8 years.
- After the 0, 1, 6 month primary immunisation schedule a booster dose may be required after 5 years after the primary course.

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. Concommitant administration of Hepatitis B immunoglobulin not necessary, but when Hepatitis B immunoglobulin is given simultaneously with Gene Vac-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 (eg needlesstick with contaminated needle) the first dose of Gene Vac-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

METHOD OF ADMINISTRATION
Gene Vac-B™ should be injected intramusculary 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.

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

PRESENTATIONS

0.5 ml	Single dose (Pediatric) vial
5 ml	10 doses (Pediatric) vial
1 ml	Single dose (Adult) vial
10 ml	10 doses (Adult) vial