เอกสารกำกับยาภาษาอังกฤษ

Hepatitis B Vaccine (rDNA)

Description

Hepatitis B vaccine (rDNA) is a non infection 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 meets the requirements of WHO when tested by the methods outlined in WHO TRS 786 (1989)

COMPOSITION

Paediatric

Each dose of 0.5 ml contains:

10 mcg of purified Hepatitis B surface antigen

Adsorbed on Aluminium hydroxide (Al^{+++}) 0.25 mg to 0.40 mg

Preservative : Thiomersal 0.005%

Produced in *Hansenula Polymorpha*(yeast)

Dose: 0.5 ml by Intramuscular injection

Adult

Each dose of 1 ml contains:

20 mcg of purified Hepatitis B surface antigen

Adsorbed on Aluminium hydroxide(Al^{+++}) 0.5 mg to 0.8 mg

Preservative: Thiomersal 0.005%

Produced in *Hansenula Polymorpha*(yeast)

Dose: 1 ml by Intramuscular injection

INDICATION

Hepatitis B Vaccine is indicated for active immunization against Hepatitis B infection in subject considered at risk of exposure to HBV material immunsation against hepatitis B is expected in the long term to reduce not only the violence of this disease. But also its chronic complication such as chronic acute hepatitis B and hepatitis B associated cirrhosis and primary hepatocellular carcinoma.

In areas of low prevalence of hepatitis B immunization with Hepatitis-B vaccine 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
- Persons at increased risk due to their sexual behaviors
- Illicit users of addictive injectable drugs
- Travelers to areas with high endemicity of HBV
- Infants born of mothers who are HBV carries
- Persons originating from areas with a high endemically of HBV
- Others Police personnel fire brigade personnel armed forces personnel and anybody who through their work of personnel 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 intermediated of high prevalence of Hepatitis B. With most of the population at risk of acquiring the disease, immunization should be offered to all neonates and young children.

Immunization 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, measles, Polio vaccine (OPV and IPV) and yellow fever vaccine. It should not be mixed in the vial or syringe with any other vaccine unless it is manufactured as a combined product (e.g. DTP-Hep B)

CONTRA-INDICATIONS

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

WARNING AND PRECAUTIONS

Because of the period of latency of hepatitis B infection it is possible for unrecognized infection to be present at the time of immunization. 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 infection response to Hepatitis B vaccines is related to ages. In general people 40 years of ages 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 immunization 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.

Hepatitis B vaccine should not be administrated in the gluteal muscle or intradermally since this may result in a lower immune response.

Hepatitis B vaccine may be used to complete a primary immunization course started either with plasma-derived or with other genetically-engineered hepatitis B vaccines.

ADVERSE REACTIONS

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 reaction include nausea, vomiting, diarrhea, abdominal pain, abnormal liver function tests, arthralgia, myalgia, rash, pruritus, urticaria, liver function.

DOSAGE AND ADMINISTRATION

Pediatric dose vaccine 10 mcg dose (in 0.5 ml suspension) is recommended for neonates or infants or in children upto 10 years of age.

Adult dose vaccine: 20 mcg dose (in 1.0 ml suspension) is recommended for adults 20 years of age or older and children above 10 years of age.

When used in children and adolescents 11-19 years of age, Hepatitis-B vaccine may be given in either 10 mcg or 20 mcg doses.

IMMUNISATION SCHEDULE

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

Two primary immunization schedules can be recommended

- A rapid schedule, with immunization 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 immunization at 0, 1 and 6 months may take longer to confer protection but will produce higher anti-HBs antibody titres

  The immunization schedule may be adapted to meet local immunization recommendation

  The following timing of injection gives general guidance

  1st dose at elected date

  2nd dose 4-20 weeks after the 1st dose

  3rd dose 1-5 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 immunization 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 immunization schedule a booster dose may be required after 5 years after the primary course

SPECIAL DOSAGE RECOMMENDATIONS

DASAGE RECOMMENDATION FOR NEONATES BORN OF MOTHERS WHO ARE HBV CARRIERS

The 0, 1, 2 month immunization 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 Hepatitis B vaccine a separate injection site must be chosen.

DOSAGE RECOMMENDATION FOR KNOWN OR PRESUMED EXPOSE OF HBV

In circumstances where exposure to HBV has recently occurred (eg needle stick with contaminated needle) the first dose of Hepatitis B immunoglobulin which however must be given at a separate injection site. The rapid immunization schedule should be advised

DOSAGE RECOMMENDATION FOR IMMUNOCOMRPROMISED PERSONS

The primary immunization 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 immunization 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

Hepatitis B vaccine (rDNA) should be injected intramusculary in the deltoid region in adults and 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. Opened multi-dose vials may be used in subsequent immunization sessions provided vaccine is stored at 2-8ºC. Opened vials which are not supplied with VVM and which have been taken out for immunization activities are discarded at the end of the day.

STORAGE

Hepatitis B vaccine (rDNA) should be stored at 2-8ºC. Do not freeze. Discard if vaccine has been frozen.

SHELF LIFE

Thirty six months from date of manufacture

PRESENTATION

0.5 ml – Single dose ampoule (Pediatric)

0.5 ml – Single dose vial (Pediatric)

5 ml – 10 dose vial (Pediatric)

1 ml – Single dose ampoule (Adult)

1 ml – Single dose vial (Adult)

10 ml – 10 dose vial (Adult)

Manufactured by

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