

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 W.H.O., TRS 978 (2013).

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 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, 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.
- Personnel and residents of institution.
- 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 carriers.
- 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 of 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 intermediated of 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, Measles, Polio vaccine (OPV and IPV) and yellow fever vaccine and vitamin A supplementation. 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-HepB).

CONTRA-INDICATIONS

Hepatitis-B vaccine 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.

WARNING 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 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 immune response to Hepatitis B vaccines is related to ages. In general, people over 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 administered 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, 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 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.

DOSAGE AND ADMINISTRATION

Paediatric dose vaccine: 10 mcg dose (in 0.5 ml suspension) is recommended for neonates, infants, children and adolescents upto 19 years of age.

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

IMMUNISATION 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 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 vaccine can be administered simultaneously with Hepatitis-B immunoglobulin which however must be given at a separate injection site. The rapid immunization schedule should be advised

DOSAGE RECOMMENDATION FOR IMMUNOCOMPROMISED 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 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. Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of Hepatitis B from which one or more doses of vaccine have been removed during an immunisation session may be used in subsequent immunisation sessions for upto a maximum of 28 days, provided that all of the following conditions are met (as described in the WHO policy statement: Handling of multi dose vaccine vials after opening, WHO/IVB/14.07):

- The vaccine is currently prequalified by WHO;
- The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO;
- The expiry date of the vaccine has not passed;
- The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

The vaccine should be visually inspected for any foreign particulate matter and/ or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

IMMUNE DEFICIENCY

Individuals infected with human immuno-deficiency virus (HIV), both asymptomatic and symptomatic, should be immunized with hepatitis B vaccine according to standard schedules.

STORAGE

Hepatitis-B vaccine (rDNA) should be stored at 2-8°C. 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 (Paediatric)

0.5 ml – Single dose vial (Paediatric)

5 ml – 10 doses vial (Paediatric)

1 ml – Single dose ampoule (Adult)

1 ml – Single dose vial (Adult)

10 ml – 10 doses vial (Adult)

MANUFACTURED BY



SERUM INSTITUTE OF INDIA PVT. LTD.

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Protection from birth onwards.

IMPORTED AND DISTRIBUTED BY

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