

SUMMARY PRODUCT CHARACTERISTICS

**Hepatitis B vaccine Adsorbed (Adult) (Hep
B Vaccine)**

DESCRIPTION	Hepatitis B vaccine (rDNA) is a known infectious recombinant DNA Hepatitis B vaccine. It contains purified surface antigen of 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 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 a preservative. The vaccine does not contain any material of human or animal origin. The vaccine meets the requirements of WHO when tested by the methods outlined in WHO TRS 978 (2013)
POTENCY	Each dose of 1ml contains: 20mcg of purified hepatitis B surface antigen Adsorbed on AlOH 0.5mg to 0.8mg Preservative: Thiomersal 0.005% Produced in Hansenula Polymorpha (yeast) Dose: 1ml intramuscular injection
THERAPEUTIC INDICATIONS	<p>Hepatitis-B Vaccine is indicated for active immunization against Hepatitis-B infection in subject considered at risk of exposure to HBV material immunization 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.</p> <p>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</p> <ul style="list-style-type: none"> - 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 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 <p>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.</p> <p>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)</p>
DOSAGE & METHOD OF ADMINISTRATION	Pediatric dose vaccine : 10 mcg dose (in 0.5 ml suspension) is recommended for neonates, infants, children and adolescents up to 10 years of age Adult dose vaccine : 20 mcg dose (1.0 ml suspension) is recommended for adults aged 10 years and above Primary Immunization. A series of three intramuscular injections is required to achieve

	optimal protection. The following immunization schedules can be recommended : - 6, 10, 14 weeks for infants - 0, 1, 6 months - 1, 2, 3 months (rapid schedule) The immunization schedule should be adapted to meet local immunization recommendations.
CONTRAINDICATIONS	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.
SPECIAL WARNINGS & PRECAUTION FOR USE	<p>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.</p> <p>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.</p> <p>The infection response to Hepatitis B vaccines is related to ages. In general people 40 years of ages respond less well.</p> <p>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 (e.g. adrenaline) should always be readily available for treatment in case of rare anaphylactic reactions following the administration of the vaccine.</p> <p>Hepatitis-B vaccine should not be administered in the gluteal muscle or intradermally since this may result in a lower immune response.</p> <p>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.</p>
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 reaction include nausea, vomiting, diarrhea, abdominal pain, abnormal liver function tests, arthralgia, myalgia, rash, pruritus, urticaria, liver function.
STORAGE OF VACCINES	Hepatitis-B vaccine (rDNA) should be stored at 2-8°C. Do not freeze. Discard if vaccine has been frozen.
PRESENTATION	<p>1ml- single dose ampoule (Adult)</p> <p>1ml- single dose vial (Adult)</p> <p>10ml-10 doses vial (Adult)</p>
MARKETING AUTHORIZATION HOLDER	Serum Institute of India, Ltd.
PRODUCT REGISTRATION NUMBER	<p>BHU-DRA/B02685</p> <p>BHU-DRA/B02686</p>