

SUMMARY PRODUCT CHARECTERISTICS

Recombinant Hepatitis B vaccine,Hepavax-Gene® TF

DESCRIPTION	Hepavax-Gene TF is a non-infectious recombinant hepatitis B vaccine. It contains highly purified hepatitis B surface antigen (HBsAg) produced by the yeast strain <i>Hansenula polymorpha</i> . HBsAg is adsorbed on aluminum hydroxide gel in physiological conditions.
POTENCY	Each dose of 1.0 ml contains 20 micrograms of HBsAg adsorbed onto 0.5 mg of aluminum hydroxide. Each dose of 0.5 ml contains 10 micrograms of HBsAg adsorbed onto 0.25 mg of aluminum hydroxide. The preparation has been treated with formaldehyde prior to adsorption onto aluminum. This vaccine is completely free of thiomersal.
THERAPEUTIC INDICATIONS	<p>Hepavax-Gene TF is indicated for active immunization against infection caused by hepatitis B virus. As infection with hepatitis D caused by the delta virus does not occur in the absence of hepatitis B infection, it is expected that Hepavax-Gene TF will also prevent form hepatitis D. The vaccine will not protect against infection caused by other agents such as hepatitis A virus, hepatitis C virus or other pathogens known to infect the liver.</p> <p>The vaccine can be administered at any age from birth onwards. Vaccination is recommended in subjects who are or will be at increased risk of infection with hepatitis B virus. These include:</p> <p>Health care personnel: Oral surgeons, dentists; physicians and surgeons; nurse, dental nurses, dental hygienists; paramedical personnel in close contact with patients; staff working in haemodialysis, haematology and oncology units; laboratory personnel handling blood and other clinical specimens; morticians and embalmers, blood bank and plasma fractionation workers; chiropodists; cleaning staff in hospital who handle waste, emergency and first aid workers; ambulance staffs.</p> <p>Patents: Patients reciving frequent blood transfuions or clothing factor concentrates such as patients in haemodialysis and oncology units, patients with thalassaemia, sickle-cell anaemia and haemophilia, etc.</p> <p>Persons at increased risk: Persons frequently changing sexual partners, including homosexually active males and Prostitutes. Illicit users of addictive injectable drugs. Travelers to high endemicity areas and their close contact. Household contacts of any of the mentioned groups above and of patients with acute or chronic hepatitis B infection. Infants born of mothers who are carriers.</p> <p>Personnel and residents of institutions Persons with frequent and/or dose contact with risk groups; prisoners and prison staff; residents and staff of institutions for the mentally disabled.</p> <p>Others: Police personnel, fire brigade personnel, military personnel and anybody who may be exposed to the hepatitis B virus through their work or personal lifestyle. In areas of intermediate or high prevalence, vaccination should be offered to all young children and neonates as well as to adults in high risk groups because most of the</p>

	<p>population is at risk for acquiring hepatitis B. Vaccination against hepatitis B is expected in the long term to reduce not only the overall incidence of hepatitis B but also chronic complications such as chronic active hepatitis and cirrhosis. It may also decrease the incidence of primary hepatocellular carcinoma.</p>
<p>DOSAGE & METHOD OF ADMINISTRATION</p>	<p>Hepavax-Gene TF is available in two dosages: Group Formulation Neonates..... 10 µg/0.5ml Infants and children up to 10 years of age..... 10 µg/0.5ml Adults and children > 10 years of age..... 20 µg/1.0ml</p> <p>Standard vaccination course The standard vaccination course consists of three intramuscular doses of vaccine: 1st dose: at elected date 2nd dose: 1 month later 3rd dose: 6th month from the date of the first dose</p> <p>Vaccination course for fast protection For neonates born to HBV infected mothers or travellers with need for short term protection or those who have or might have been recently exposed to the virus, the recommended schedule is 0, 1 and 2 months. On this alternate schedule, a booster dose at 12 months is recommended for prolonged protection. A full course of vaccination will provide protection for several years. A boosting may be required after successful vaccination, according to official guidance. Hepavax-Gene TF should be injected intramuscularly. In adults the injection should be given in the deltoid muscle but it may be preferable to inject Hepavax-Gene TF in the anterolateral thigh in neonates and infants because of the small size of their deltoid muscle. The vaccine may be administered subcutaneously in patients with severe bleeding tendencies (e.g. haemophiliacs). The vaccine should be shaken before use. In case of known or presumed exposure to the Hepatitis B virus, Hepavax-Gene TF may be administered simultaneously with hepatitis B Immunoglobulin, but must be given at a separated injection site.</p>
<p>CONTRAINDICATIONS</p>	<p>Hypersensitivity to any component of the vaccine. As for other vaccines, Hepavax-Gene TF should not be administered to subjects with severe febrile infections. However, the presence of a minor infection is not a contraindication for a vaccination with Hepavax-Gene TF.</p>
<p>SPECIAL WARNINGS & PRECAUTION FOR USE</p>	<p>Precautions The effect of the antigen on foetal development is unknown and therefore general vaccination of pregnant women cannot be recommended. However, vaccination of pregnant women may be considered in order to prevent hepatitis B in high-risk situations. As with all biological products, epinephrine should always be readily available for immediate use in case of a rare anaphylactic reaction.</p> <p>Warnings Because of the long incubation period of hepatitis B an unrecognized infection with the hepatitis B virus might be present at the time of vaccination. The vaccine may not prevent hepatitis B in such cases.</p>

	<p>Hepavax-Gene TF should not be administered in the gluteal region or intradermally since these routes of administration may not result in an optimum immune response. The vaccine should not be administered intravenously.</p> <p>In dialysis patients and subjects who have an impairment of the immune system, adequate antibody concentrations may not be obtained after the usual primary vaccination course and such patients may therefore require repeated administrations of the vaccine.</p>
INTERACTION WITH OTHER MEDICAL PRODUCTS & OTHER FORM OF INTERACTION	<p>Since Hepavax-Gene TF is a noninfectious, inactivated product, concomitant administration of Hepavax-Gene TF and other killed vaccines is not likely to cause interference with the immune response to these vaccines.</p> <p>Hepavax-Gene TF can be given concurrently with diphtheria and tetanus toxoids and pertussis vaccine adsorbed (DPT) or poliovirus vaccine live oral (OPV), but the vaccines should be given with different syringes and at different sites.</p>
PREGNANCY & LACTATION	<p>It is not known whether Hepavax-Gene TF is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a lactating mother.</p>
UNDESIRABLE EFFECTS	<p>The most common reported local reactions are soreness, erythema and swelling at the injection sites as seen with all adsorbed vaccines. These reactions are mild and usually subside within two days of vaccination.</p> <p>Uncommon systemic complaints: fever, headache, nausea, dizziness and fatigue have been observed in some vaccinees, but a causal relationship with the vaccine has not been established.</p>
STORAGE OF VACCINES	<p>The shelf-life of Hepavax-Gene TF is 36 months from the date of manufacturing To be stored at 2 to 8 °C</p>
PRESENTATION	<p>As single dose vial of vaccine: 20 µg/1.0 ml vial x 1, 50 10 µg/0.5 ml vial x 1, 50</p>
MARKETING AUTHORIZATION HOLDER	<p>Berna Biotech Korea Corp.</p>
PRODUCT REGISTRATION NUMBER	<p>BHU-DRA/B02992</p>