

SUMMARY PRODUCT CHARECTERISTICS

Hepatitis B Vaccine, Recombinant (Trade Name:Euvax B inj)

DESCRIPTION	Euvax B vaccine is a white, slightly opalescent suspension. It is a subunit viral vaccine containing highly purified, non-infectious particles of hepatitis B surface antigen (HBsAg) adsorbed onto Aluminum salts as an adjuvant. Thiomersal (0.01% w/v) is used as a preservative. It is a DNA recombinant vaccine derived from HBsAg produced by DNA recombinant technology in yeast cells (<i>Saccharomyces cerevisiae</i>). The vaccine fulfills WHO requirements for recombinant hepatitis B vaccine. No substance of human origin is used in the manufacture.
POTENCY	1 ml of above vaccine contains: Active ingredient: Purified HBsAg 20µg Adjuvant: Aluminum Hydroxide Gel (As Aluminum) 0.5mg Preservative: Thiomersal 0.01% w/v Excipients: Potassium phosphate, monobasic, sodium phosphate, dibasic, sodium chloride
THERAPEUTIC INDICATIONS	Immunization against infections caused by all known subtypes of Hepatitis B virus.
DOSAGE & METHOD OF ADMINISTRATION	<p>It should be injected intramuscularly into the anterolateral aspect of the thigh in infants, or into the deltoid muscles of older children or adults.</p> <p>-One dose is 0.5ml containing 10µg of HBsAg. The minimum regimen consist of three doses of vaccines given according to the following schedule:</p> <ol style="list-style-type: none"> 1. 1st dose: at elected date 2. 2nd dose: 1 month after first dose 3. 3rd dose: 6 month after first dose <p>Booster vaccination: the WHO does not recommend booster vaccination, as it has been shown that 3 dose series of Hepatitis B immunization protects for as long as 15 years, and that a protective anamnestic response occurs after exposure to HBV, even if protective antibodies have been lost over time. However, some local vaccination programs worldwide currently include a recommendation for a booster dose, and these should be respected.</p> <p>An alternative, 0-1, and 2-month schedule and a 12 month booster may be used in certain populations (i.e., neonates born from Hepatitis B infected mothers, someone who has or might have been recently exposed to the virus or certain travelers to high risk areas).</p> <p>Additional dose(s) of vaccine may be required in hemodialysis or immunodeficient patients, since protective antibody titer (>10IU/L) may not be obtained after primary immunization course.</p> <p>In case of known or presumed exposure to Hepatitis B virus (e.g., neonates born of infected mothers, others experiencing percutaneous or permucosal exposure), a first dose of immunoglobulin can be given. The anti-HBs immune response may be reduced and the titers should be followed up after immunization of immunocompromised individuals, where possible.</p> <p>In countries where perinatal transmission of Hepatitis B is common, a first dose should be given as soon as possible after birth. If perinatal transmission is uncommon, or if at delivery at birth is not feasible, the 1st dose can be given with the 1st dose of DTP vaccine. The 2nd dose should be administered 1 month after the 1st dose. The 3rd dose should be administered 1-12 months after the 2nd dose.</p> <p>Hepatitis B vaccine can be given safely and effectively at the same time as BCG, DTP, Measles, Polio vaccines (IPV or OPV), or Hib or Yellow fever vaccines. If Hepatitis B vaccine is given at the same time as other vaccines, it should be administered at a separate site. It should not be mixed in the vial or syringe with any other vaccines unless</p>

	<p>it is manufactured as a combined product (e.g DTP-HepB.) Once opened, multidose vial should be kept between 2°C and 8°C. Opened vials may be used subsequent immunizations sessions, provided that following conditions are met:</p> <ol style="list-style-type: none"> 1. The expiry date has not passed 2. The vaccines have been stored under proper cold chain conditions (2-8°C) 3. Opened vials of vaccines, which are not supplied with VVM and which have been taken out of the health center for immunization activities (e.g. outreach or supplementary immunization activities) are discarded at the end of the day. <p>An opened vial must be discarded immediately if any of the following conditions applies:</p> <ol style="list-style-type: none"> 1. Sterile procedures have not been fully observed. 2. There is suspicion that the opened vial has been contaminated. 3. There is visible evidence of contamination, such as change in appearance or floating particles.
CONTRAINDICATIONS	<p>Hepatitis B vaccine is contraindicated for use in persons with hypersensitivity to any component of Euvax B. The vaccine will not harm individuals currently or previously infected with HB virus. Individuals with human immunodeficiency virus infection (HIV) both symptomatic and asymptomatic should be immunized with hepatitis B vaccine according to standard schedule.</p>
SPECIAL WARNINGS & PRECAUTION FOR USE	<p>General Precautions:</p> <ol style="list-style-type: none"> 1. The administration of EuVax B Vaccine should be postpone in patients suffering from acute, severe febrile illness. 2. In patients suffering from multiple sclerosis, any stimulation of the immune system can induce exacerbation of their symptoms. Therefore, for these patients the benefits of vaccination against Hepatitis B should be outweighed against the risk of exacerbation of multiple sclerosis. 3. It is considered that protection cannot be obtained by a vaccination can be obtained by vaccination in patients in latent or progressive states of Hepatitis B. 4. As with all injectible vaccines, appropriate medical treatment should always be readily available in case of rare anaphylaxis following the administration of vaccine. <p>Precaution for usage:</p> <ol style="list-style-type: none"> 1. Shake before administration, since a fine deposit with a clear, colorless supernatant may form during storage. 2. A sterile syringe and sterile needle should be used for each injection.
ADVERSE REACTIONS	<p>Common: Local reactions such as erythema, pain, swelling or minor fever may occur rarely; these symptoms disappear in 2 days.</p> <p>Rare: Hyperthermia (above 38.8°C); Systemic reaction such as malaise, asthenia, headache, nausea, vomiting, dizziness, myalgia, arthritis, skin rash and transient increase of transaminases.</p> <p>Very rare: A casual sequence of cause and effect could not be established for reports of multiple neuritis, optic neuritis, facial paralysis, exacerbation of multiple sclerosis and Guillain-Barre syndrome.</p>
PREGNANCY & LACTATION	<p>The effect of HBsAg on fetal development has not been assessed. However, as with all inactivated viral vaccines, the risk to the fetus is considered to be negligible. Euvax B should be used in pregnancy only when clearly needed. The effect on breast-fed infants of the administration of Euvax B to their mothers has not</p>

	been evaluated in clinical studies. No contraindication has been established.
STORAGE OF VACCINES	Do not exceed the expiry date stated on external packaging. Store between 2°C-8°C in refrigerator. DO NOT FREEZE.
PRESENTATION	Single dose vials or vials of 10 dose.
MARKETING AUTHORIZATION HOLDER	LG-Life sciences, Korea
PRODUCT REGISTRATION NUMBER	BHU-DRA/B02312