

100*150mm(front)

100*150mm(back)


LG Chem pharmaniaga®

LPIS00090A-1

Euvax B

HEPATITIS B VACCINE, RECOMBINANT

Euvax B consists of highly purified, non infectious particles of Hepatitis B surface antigen (HBsAg) adsorbed onto aluminum salts as an adjuvant. It is a recombinant DNA hepatitis B vaccine derived from HBsAg produced by DNA recombinant technology in yeast cells (*Saccharomyces cerevisiae*).

The vaccine meets the WHO requirements for recombinant hepatitis B vaccines. No substances of human origin are used in its manufacture.

DESCRIPTION

Euvax B is a white, slightly opalescent suspension.

COMPOSITION

1 ml of the above vaccine contains :

- Active ingredient : Purified HBsAg 20 µg
- Adjuvant : Aluminum Hydroxide Gel (as Al) 0.5 mg
- Excipients : Potassium phosphate, monobasic, Sodium phosphate, dibasic, Sodium chloride, WFI

INDICATION AND USAGE

Immunization against infection caused by all known subtypes of Hepatitis B virus.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Higher antibody titers and lower ED₅₀ values were observed with Euvax B in mice than with plasma-derived HBsAg and also higher antibody titers than with commercially available rHBsAg in a comparison test to assess the potency of Euvax B (Table 1, 2).

Table 1 Potency test of rHBsAg in mice

	Reference plasma-derived HBsAg vaccine	Euvax B recombinant HBsAg vaccine
ED ₅₀ (µg/mL)	0.13	0.09

Table 2 Potency test of rHBsAg in Guinea pigs

	Engerix B (recombinant HBsAg vaccine)	Euvax B (recombinant HBsAg vaccine)
GMT* (mIU/mL)	32.76	58.87

*GMT : Geometric Mean Titer

Relevant information for Euvax B

In order to evaluate the immunogenicity and safety of recombinant DNA yeast-derived hepatitis B vaccine (Euvax B™) by administration at intervals of 0-, 1-, and 2-months and 0-, 1-, and 6-months and to compare the antibody titers after vaccination by a plasma-derived HBV vaccine with that by the recombinant HBV vaccine, 5 clinical trials were conducted among healthy Koreans.

Several different parameters were compared in these studies: difference in age and sex distribution, seroconversion rate, geometric mean titers between the experimental vaccine group (Euvax B) and control vaccine group (plasma-derived vaccine), as well as safety in the Euvax B group. When small differences in sex and age distribution were observed, they had no consequence on the ability to compare between-group immunogenicity. There was no difference in the immunogenicity between the two groups when the same vaccination schedule was compared, but the 0-, 1-, and 6-month schedule was considered to be better than the 0-, 1-, and 2-month schedule for long-term immunogenicity. The immunogenicity of the recombinant HBV vaccine was as good as the plasma-derived HBV vaccine, when considering the seroconversion rates and the antibody titer levels. There was no case observed of HBsAg seropositivity or episode of clinical hepatitis among study subjects during these studies. Adverse reactions observed in study groups after vaccination were mild and symptoms were temporary. Overall, available data indicate that immunization against hepatitis B using the yeast-derived recombinant hepatitis B vaccine produced by LG Chem, Ltd. (Euvax B™) is efficacious for both the 2- and the 6-month schedules, making it possible to choose between the 2- and the 6-month schedule according to the vaccine's convenience. The safety and immunogenicity of Euvax B was documented in all age groups.

Preclinical safety data

Appropriate safety tests have been performed and available data reveals no special hazard for humans.

DOSAGE AND ADMINISTRATION

Euvax B is for intramuscular use only.

- One pediatric dose (neonates, infants, and children aged up to and including 15 years of age) is 0.5 ml containing 10 µg of HBsAg.
- One adult dose (from 16 years) is 1.0 ml containing 20 µg of HBsAg.

The immunization regimen consists of three doses of vaccine given according to the following schedule;

- 1st dose : at elected date
- 2nd dose : 1 month after the first dose
- 3rd dose : 6 months after the first dose

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 programmes worldwide currently include a recommendation for a booster dose, and these should be respected.

An alternative 0, 1 and 2 months schedule and a 12 months booster can be used in certain populations (e.g. neonates born from Hepatitis B-infected mothers, someone who has or might have been recently exposed to the virus, certain travelers to high-risk areas). Additional dose(s) of vaccine may be required in hemodialysis or immunodeficient patients since protective antibody titers (> 10 IU/l) may not be obtained after the primary immunization course.

INTERACTION WITH OTHER MEDICAMENTS

Generally, hepatitis B vaccine can be concomitantly administered with BCG, DTP, measles, Polio vaccine using at different injection site.

CONTRAINDICATIONS

Hepatitis B vaccine is contraindicated for use in persons with hypersensitivity to any component of Euvax B.

WARNINGS AND PRECAUTIONS

General precautions :

- The administration of Euvax B should be postponed in patients suffering from acute severe febrile illness.
- 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 weighed against the risks of exacerbation of multiple sclerosis. (see Adverse Reactions).
- It is considered that protection cannot be obtained by vaccination in patients in latent or progressive state of Hepatitis B.
- As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.
- The administration of Euvax B induces a local inflammatory reaction at the injection site after intramuscular injection, of a type and severity that are to be expected with this type of vaccine formulation.
- Thimerosal (an organomercuric compound) has been used in the manufacturing process of this medicinal product and residues of it are present in the final product. Therefore, sensitization reactions may occur.
- In preterm babies (<2,000 grams), it is advisable to check antibody titers one month after the third dose to assess the need for a booster dose.

SYMPTOMS AND TREATMENT OF OVERDOSE

- Symptoms and treatment of overdose of Euvax B has not been reported.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

- Hepatitis B vaccine is unlikely to produce effect on ability to drive and use machines.

PRECAUTIONS FOR USAGE

- Shake before administration, since a fine white deposit with a clear colorless supernatant may form during storage.
- Euvax B should not be administered in the gluteal region and it must not be administered intravenously.

PREGNANCY AND LACTATION

- The effect of the HBsAg on foetal development has not been assessed. However, as with all inactivated viral vaccines, the risks to the foetus are considered to be negligible. Euvax B should be used during pregnancy only when clearly needed.
- The effect on breast-fed infants of the administration of Euvax B to their mothers has not been evaluated in clinical studies. No contraindication has been established.

ADVERSE REACTIONS

Gastrointestinal disorders:

Rare: nausea

Common: abdominal pain, diarrhea, vomiting

General disorders and administration site conditions:

Rare: malaise, fatigue

Common: fever, induration, oedema, tenderness, inflammation

Infections and infestations:

Very common: injection site pain

Uncommon: moniliasis, rhinitis

Investigations:

Rare: transient increase of transaminase

Metabolism and nutrition disorders:

Common: anorexia

Musculoskeletal and connective tissue disorders:

Rare: myalgia, arthritis

Nervous system disorders:

Very rare: optic neuritis, facial paralysis, Guillain-Barre syndrome, aggravation of disseminated sclerosis

Rare: headache, dizziness

Pregnancy, puerperium and perinatal conditions

Common: crying abnormal, somnolence

Psychiatric disorders:

Uncommon: jaundice neonatal

Skin and subcutaneous tissue disorders:

Common: insomnia, nervousness, irritability

Common: rash erythematous, erythema

Uncommon: pityriasis rosea, rash, rash maculo-papular

Common: hematoma

Vascular disorders:

STORAGE CONDITIONS

Do not exceed the expiry date stated on the external packaging.

Euvax B is stable for 36 months at 2-8°C.

It can be used safely for 36 months when stored at 2-8°C in a refrigerator.

It should not be frozen.

PRESENTATIONS

0.5 ml/vial x 20 vials - 0.5 ml/vial x 1 vial

1.0 ml/vial x 20 vials - 1.0 ml/vial x 1 vial

Issuance date : 07.11.2023

Product Registration Holder

Pharmaniaga Marketing Sdn. Bhd.

(198401005734)
No. 7, Lorong Keluli 1B,
Kawasan Perindustrian Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam
Selangor Malaysia

Manufactured by

LG Chem, Ltd.

151, Osongsaengmyeong 1-ro,
Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do,
Republic of Korea

자재명(코드) 설명서 EUVAX 공통 TMF 말레이시아 (Public) (LPIS00090A)

자재명(코드)	변경전	변경후
버전	-	1
사이즈(mm)	-	100*150
재질	-	45g모조
(최소) 글씨 크기	-	주소 글씨 크기 4 point
개정연월일	-	07.11.2023
주된 변경내용	-	제정
비고	-	

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Selangor Malaysia

Manufactured by

LG Chem, Ltd.

151, Osongsaengmyeong 1-ro,
Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do,
Republic of Korea

설명서 EUVAX 공통 TMF 말레이시아 (Private) (LPIS00091A)

자재명(코드)	설명서 EUVAX 공통 TMF 말레이시아 (Private) (LPIS00091A)	
	변경전	변경후
버전	-	1
사이즈(mm)	-	100*150
재질	-	45g모조
(최소) 글씨 크기	-	주소 글씨 크기 4 point
개정연월일	-	07.11.2023
주된 변경내용	-	제정
비고	-	