Informasi Untuk Pasien

Euvax B

Rec. HepB vaccine
Suspensi untuk Injeksi Intramuskular

Vaksin ini memerlukan pengawasan tambahan. Ini akan memberikan identifikasi yang cepat atas informasi keselamatan yang baru. Anda dapat membantu dengan melaporkan efek samping yang mungkin Anda dapatkan. Lihat bagian akhir dari Bagian 4 tentang bagaimana melaporkan efek samping.

Baca brosur ini secara hati-hati sebelum Anda atau anak Anda divaksinasi karena berisi informasi penting bagi Anda.
- Simpan brosur ini, mungkin Anda perlu membaca brosur ini kembali.
- Jika ada pertanyaan lebih lanjut, tanyakanlah kepada dokter, apoteker, atau perawat Anda.
- Vaksin ini diresepkan untuk Anda atau anak Anda. Jangan diberikan pada orang lain.
- Jika ada efek samping pada Anda atau anak Anda, bicarakanlah pada dokter, apoteker, atau perawat. Hal ini termasuk kemungkonan efek samping apapun yang tidak tercantum dalam selebaran ini. Lihat bagian 4.

Ada apa dalam selebaran ini

1. Apa itu Euvax B dan digunakan untuk apa

Euvax B digunakan untuk pencegahan infeksi Hepatitis B. Vaksin ini bekerja dengan menstimulasi tubuh untuk memproduksi antibodi terhadap infeksi Hepatitis B.

2. Hal yang perlu Anda ketahui sebelum Anda atau anak Anda menggunakan Euvax B

Jangan gunakan Euvax B:
- Jika Anda hipersensitif (alergi) terhadap Purified HBs Antigen atau bahan lain dari Euvax B, termasuk ragi dan merkuri
- Jika Anda pernah memiliki reaksi alergi terhadap vaksin Hepatitis B di masa lalu
- Jika Anda sedang hamil
- Jika Anda memiliki sistem kekebalan tubuh yang lemah, memiliki penyakit yang dapat mempengaruhi sistem kekebalan tubuh Anda, atau sedang menjalani pengobatan terapi imunosupresif.

Berhati-hatilah dalam penggunaan Euvax B
- Jika Anda memiliki penyakit jantung atau paru-paru

Disetujui Oleh BPOM : 19/05/2026

ID : EREG100022VR12600093
EREG100022VR12600095

- Jika Anda menderita penyakit yang menyebabkan demam atau reaksi sistemik yang dapat menimbulkan risiko signifikan
- Jika anda seorang ibu menyusui
- Jika Anda sedang menderita demam atau infeksi

Karena masa inkubasi Hepatitis B yang panjang, infeksi yang tidak terdeteksi mungkin sudah ada pada saat Euvax B diberikan. Euvax B tidak dapat mencegah Hepatitis B pada pasien tersebut.

Efek dalam berkendara dan menjalankan mesin
Belum ada studi yang dilakukan terkait ini.

3. Bagaimana cara menggunakan Euvax B

Euvax B hanya dapat disuntikkan ke otot. Obat ini TIDAK boleh diinjeksikan ke kulit atau pembuluh darah.

Bayi baru lahir dan anak berusia 10 tahun atau lebih muda:..... 0,5 mL (10 µg)
Dewasa dan anak-anak di atas 10 tahun: ..... 1,0 mL (20 µg)

Jadwal imunisasi dasar terdiri dari 3 suntikan ke otot:
Injeksi ke-1: sekarang (usia 6 minggu untuk bayi baru lahir)
Injeksi ke-2: 1 bulan kemudian
Injeksi ke-3: 6 bulan setelah suntikan pertama

Jadwal imunisasi alternatif dapat digunakan untuk kelompok risiko tinggi tertentu seperti bayi baru lahir dari ibu yang terinfeksi Hepatitis B, orang yang baru saja terpapar atau mungkin terpapar virus tersebut (misalnya petugas kesehatan atau petugas lain yang melakukan kontak langsung dengan pasien atau cairan tubuhnya); pasien yang memerlukan hemodialisis; penderita hemofilia dan mereka yang menerima transfusi darah atau produk darah secara teratur.

Orang yang berisiko tinggi tertular Hepatitis B adalah termasuk orang yang memiliki kontak atau pasangan seksual dari kasus pembawa Hepatitis B, individu yang sering berganti pasangan seksual, pecandu obat parenteral dan wisatawan ke daerah berisiko tinggi.

Jadwal imunisasi alternatif terdiri dari 3 suntikan ke otot:
Injeksi ke-1: sekarang
Injeksi ke-2: 1 bulan kemudian
Injeksi ke-3: 2 bulan setelah dosis pertama

Injeksi harus diberikan di tempat-tempat berikut:
Dewasa: Otot bagian atas lengan
Bayi: Otot paha

Dokter atau perawat akan mengocok vaksin dengan baik sebelum digunakan dan vaksin tidak boleh digunakan jika tampak berubah warna atau menggumpal.

Jika terjadi overdosis, konsultasikan dengan dokter atau apoteker Anda. Jika tidak ada keduanya, segera cari pertolongan medis rumah sakit atau pusat kontrol keracunan terdekat.

Harap Kembali untuk memperoleh injeksi pada jadwal yang direkomendasikan. Jika Anda terlupa untuk menerima dosis injeksi sesuai jadwal, segera hubungi dokter Anda.

4. Efek samping yang mungkin terjadi

Semua obat dapat menimbulkan efek yang tidak diinginkan

Segera cari pertolongan medis jika terjadi reaksi alergi berat (ruam; gatal-gatal; kesulitan bernapas; sesak dada; pembengkakan mulut; wajah; bibir; atau lidah).

Periksakan kepada dokter, apoteker, atau tenaga Kesehatan Anda, jika salah satu dari efek samping yang tidak diinginkan ini menetap atau menjadi lebih parah;

- Kemerahan, nyeri, bengkak, atau rasa sakit di tempat injeksi. Efek samping tersebut umumnya akan hilang dalam waktu 48 jam.
- Rasa tidak nyaman, lemah, lelah, sakit kepala, mual, muntah, demam, pusing, nyeri atau nyeri otot dan nyeri sendi.

Tidak semua efek samping yang dilaporkan untuk obat ini telah disertakan dalam Informasi Untuk Pasien. Jika Kesehatan Anda memburuk saat menggunakan obat ini, konsultasikan dengan dokter, apoteker atau tenaga kesehatan lainnya.

Pelaporan efek samping

~~Segera laporkan apabila Anda mengalami keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat kepada farmakovigilans@kalventis.com. Laporan Anda dapat membantu memberikan informasi terkait keamanan obat ini.~~

Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker. Efek samping ini termasuk efek samping apapun yang mungkin muncul yang tidak tercantum pada leaflet ini. Anda juga dapat melaporkan efek samping secara langsung ke Industri Farmasi dengan kontak berikut farmakovigilans@kalventis.com. Dengan melaporkan efek samping Anda dapat membantu memberikan informasi tentang keamanan obat ini.

5. Interaksi obat

Data interaksi obat tidak tersedia.

6. Bagaimana cara menyimpan Euvax B

Jauhkan obat dari jangkauan dan pandangan anak-anak.

Simpan dalam lemari pendingin (2°C – 8°C). Jangan dibekukan.

Kocok dengan baik sebelum digunakan. Pengadukan menyeluruh pada saat pemberian diperlukan untuk menjaga keseragaman suspensi vaksin.

Jangan gunakan produk tersebut setelah tanggal kedaluwarsa yang tertera pada botol atau karton.

Kembalikan semua obat yang tidak terpakai ke apoteker Anda. Jangan buang obat yang tidak terpakai ke saluran pembuangan atau sistem pembuangan kotoran (misalnya toilet).

7. Isi dan kemasan dan informasi lainnya

Apa isi dari Euvax B

Satu dosis (1,0 mL) Euvax B Adult mengandung:

Bahan aktif:

- Purified HbS Antigen 20 micrograms

Bahan tambahan
- Aluminium Hydroxide Gel
- Potassium Phosphate Monobasic
- Sodium Phosphate Dibasic
- Sodium Chloride
- Distilled Water for Injection

Satu dosis (0,5 mL) Euvax B Pediatric mengandung:
Bahan aktif:
- Purified HbS Antigen 10 micrograms

Bahan tambahan
- Aluminium Hydroxide Gel
- Potassium Phosphate Monobasic
- Sodium Phosphate Dibasic
- Sodium Chloride
- Distilled Water for Injection

Seperti apa Euvax B dan isi kemasannya
Euvax B berbentuk suspensi putih keruh dalam vial transparan

Kemasan:
Euvax B (Pediatric)
Dus, 1 vial @ 0,5 mL (1 dosis)
No. Registrasi: ~~DKI2401300443A1~~DKI2501300543A1

Euvax B (Adult)
Dus, 1 vial @ 1,0 mL (1 dosis)
No. Registrasi: ~~DKI2401300443B1~~DKI2501300543B1

Diproduksi oleh:
LG Chem, Ltd.
151, Osongsaengmyeong 1-ro, Osong eup, Heungdok-gu,
Cheongju-si, Chungcheongbuk-do, Republic of Korea

Diimpor & Didistribusikan oleh:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Harus Dengan Resep Dokter

Disetujui Oleh BPOM : 19/05/2026
ID : EREG100022VR12600093
EREG100022VR12600095

EUVAX B

HEPATITIS B VACCINE, RECOMBINANT

Euvax B consist of highly purified, ~~non infectious~~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

0.5 mL of the above vaccine contains:

- Active ingredient: Purified HBsAg……~~,~~…10 µg
- Adjuvant : Aluminum Hydroxide Gel (as Al)……0.25 mg
- Excipients: Potassium phosphate, monobasic~~,~~; Sodium phosphate, dibasic~~,~~; Sodium Chloride

INDICATION AND USAGE

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

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC

Pharmacoterapeutic group: Hepatitis B, purified antigen
ATC code: J07BC01

Mechanism of Action:

Infection with hepatitis B virus can have serious consequences including acute massive hepatic necrosis and chronic active hepatitis. Chronically infected persons are at increased risk for cirrhosis and hepatocellular carcinoma.

Antibody concentrations ≥10 mIU/mL against HBsAg are recognized as conferring protection against hepatitis B virus infection.

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. In addition, a small-scale clinical trial was done in Vietnam to evaluate the immunogenicity and safety of Euvax B.
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 considerd 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 where 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 Life Sciences 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 vaccinee's convenience. The safety and immunogenicity to Euvax B was documented in all age groups.

Preclinical safety data

The toxicity of Euvax B has been studied in single-dose studies (oral and intraperitoneal) in the rat and mouse, and in repeat-dose studies up to 4 weeks duration in the rat (subcutaneous). The mutagenic potential of Euvax B was tested in the Ames bacterial mutation test, chromosomal aberration test and micronucleus test. A series of antigenicity studies have been conducted, as well as the passive cutaneous anaphylaxis (PCA) test in the mouse-rat systems and the guinea pig-guinea pig system, plus active systemic anaphylaxis in the guinea pig. In addition, the tests of local irritation of Euvax B was conducted in the rabbit.

In acute studies, mice and rats received a single oral or intraperitoneal dose of 0. 0.125, 0.25, 0.5, 1, or 2 mg/kg body weight. The LD50 values in male and female mice were > 2 mg/kg (50 ml/kg), and were the ~~sate~~state in rats. There were no changes in death rate or weight cause by the test material. Any abnormalities in clinical findings and at necropsy also were observed in the control group, so it is considered that they were not specific reactions caused by the test material itself. In conclusion, acute toxicological effect of Euvax B on rats and mice was negligible.

In subacute studies, rats received 4 weeks treatment (5 times per week) by subcutaneous route at doses of 0, 50, 100, or 200 µg/kg. There were no toxicologically significant, treatment-related changes in clinical findings, body weight, food consumption, water consumption, hematology, blood chemistry, gross findings on necropsy, and organ weights. In conclusion, no important treatment related abnormalities were observed.

The potential for Euvax B to induce genetic damage was investigated in in vitro studies. The results demonstrated the lack of mutagenic potential of Euvax B. The induction of reverse mutations in *Salmonella typhimurium* according to the method of Ames was conducted, both with and without metabolic activation, at Euvax B concentrations ranging between 10 and 2000 ng/plate. Euvax B at any concentration did not induce an increase in the number of colonies with reverse mutation.

The induction of chromosomal aberration was evaluated in cultures of Chinese hamster cell lung fibroblast at an Euvax B concentration range of 5, 10, and 20 µL/mL. Chromosomal aberration was not observed.

The induction of micronucleus formation in bone marrow cells was evaluated in the rat at Euvax B concentration range of 0.1, 0.2 and 0.4 mg/kg. There was no significant increase of micronuclei in the Euvax B treated groups.

In a rat/mouse passive cutaneous anaphylaxis (PCA) test, serum from mice sensitized with Euvax B produced no responses in challenged rats. In a guinea pig active anaphylaxis test, Euvax B showed some potential to induce mild anaphylactic responses like urination or defecation. In a guinea pig passive cutaneous anaphylaxis (PCA) test, serum from guinea pigs sensitized with Euvax B produced no response in challenged guinea pigs. In conclusion, Euvax B showed no antigenicity in studies using the PCA test, and it showed a low potential for antigenicity in the guinea pig active anaphylaxis test.

In a local irritation test in the rabbit the Primary Irritation Index (P.I.I) of Euvax B following the Draize method was 0 under the experimental conditions, and it is concluded that Euvax B is without skin irritation properties.

DOSAGE AND ADMINISTRATION

Euvax B is for intramuscular 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 the exposure to HBV, even if protective antibodies have been lost over time. However, some local vaccination ~~programmes~~programs 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.

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.
- 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.
- 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.
- 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.

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-feed infants of the administration of Euvax B to their mothers has not been evaluated in clinical studies. No contraindication has been established.

Effects on the ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

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 Very common: injection site pain
Infections and infestations:	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 Common: crying abnormal, somnolence
Pregnancy, puerperium and perinatal conditions:	Uncommon: jaundice neonatal
	Common: insomnia, nervousness, irritability
Skin and subcutaneous tissue disorders:	Common: rash erythematous, erythema Uncommon: pityriasis rosea, rash, rash maculo-papular
Vascular disorders:	Common: hematoma

Reporting of suspected adverse reactions

~~Report immediately if you experience any adverse reaction or undesirable condition during and after using the medicinal product to farmakovigilans@kalventis.com~~

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reaction via farmakovigilans@kalventis.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan. Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560

Email: pvcenter@pom.go.id

Phone: +62-21-4244691 Ext.1079

Website: https://e-meso.pom.go.id/

DRUG INTERACTIONS

Drug interaction data is not available.

STORAGE CONDITIONS

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

Store between +2°C and +8°C (in a refrigerator). Do not freeze. Shelf-life is 36 months.

PRESENTATIONS

Box, 1 vial @ 1 dose (0.5 mL) [Pediatric]
Reg. No. DKI2501300543A1

Box, 1 vial @ 1 dose (1 mL) [Adult]
Reg. No. DKI2501300543B1

~~Box, 1 vial @ 1 dose (1 mL) [Adult]~~

~~Issuance date: 08 March 2025~~Approval date: Based on approval BPOM dated xxx - Standar Informasi Obat (SIO)

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

~~Reg No.: DKI2401300443A1~~
~~DKI2401300443B1~~

Manufactured by
LG Chem, Ltd.
151, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea

Imported & Distributed by
PT Kalventis Sinergi Farma
Jakarta, Indonesia