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 and thimerosal as a preservative in multidose vials only.

INDICATION AND USAGE

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

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 immunisation 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.

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.
- Thimerosal (an organomercuric compound) has been used in manufacturing process of this medicinal 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.
- 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.

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

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

Psychiatric disorders

Common: insomnia, nervousness, irritability

Skin and subcutaneous tissue disorders

Common: rash erythematous, erythema

Uncommon: pityriasis rosea, rash, rash maculo-papular

Vascular disorders

Common: hematoma

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.

PRESENTATIONS

0.5 ml/vial x 20 vials - 0.5 ml/vial x 1 vial - 0.5 ml/vial x 10 vials

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

5 ml/vial x 10 vials

10 ml/vial x 10 vials

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Manufactured by

LG Chem

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