Euvax B consists of highly purified, non infectious particles of Hepatitis B surface antigen (HBsAg) adsorbed onto aluminum salts as an adjuvant and preserved with thimerosal. It is a recombinant DNA hepatitis B vaccine derived from HBV 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
- Preservative: Thimerosal 0.01 w/v%
- Excipients: Potassium phosphate, monobasic, Sodium phosphate, dibasic, Sodium chloride.

**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 vaccines may provide lifelong protection. Therefore, for patients whose protection is threatened, a booster dose is not always effective.

**CONTRAINDICATIONS**

Euvax 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 stage of Hepatitis B.

**With all available vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

**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**

Common:
- Local reactions such as erythema, pain, swelling or minor fever may rarely occur; these symptoms disappear in 2 days.
- Rare:
  - Myalgia (above 38°C).
  - Systemic reactions such as malaise, headaches, nausea, vomiting, dizziness, myalgia, anorexia.

**Precautions for use**

- 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.

**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
1 ml/vial x 20 vials - 1 ml/vial x 1 vial
5 ml/vial x 10 vials - 10 ml/vial x 10 vials

**Issuance date:** 1998.2.6
**Revised date:** 2003.12.15

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