طبقاً لـ WHO

Euvax B inj.

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 and preserved with thimerosal. 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 aluminum) ---------- 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 should be injected intramuscularly into the deltoid muscle of older children or adults.
- 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:
- 1 st dose: at elected date
- 2nd dose: 1 month after the first dose
- 3rd dose: 6 month 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-month schedule and a 12-month booster may 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, or 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. The vaccine will not harm individuals currently or previously infected with HB virus. Individuals infected with human immunodeficiency virus (HIV), both asymptomatic and symtomatic, should be immunized with hepatitis B vaccine according to standard schedules.

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.
- 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.

Precautions for usage:

- Shake before administration, since a fine white deposit with a clear colorless supernatant may form during storage.
- A sterile syringe and sterile needle should be used for each injection.

Pregnancy and lactation

- The effect of the HBsAg on fetal development has not been assessed. However, as with all inactivated viral vaccines, the risks to the fetus 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

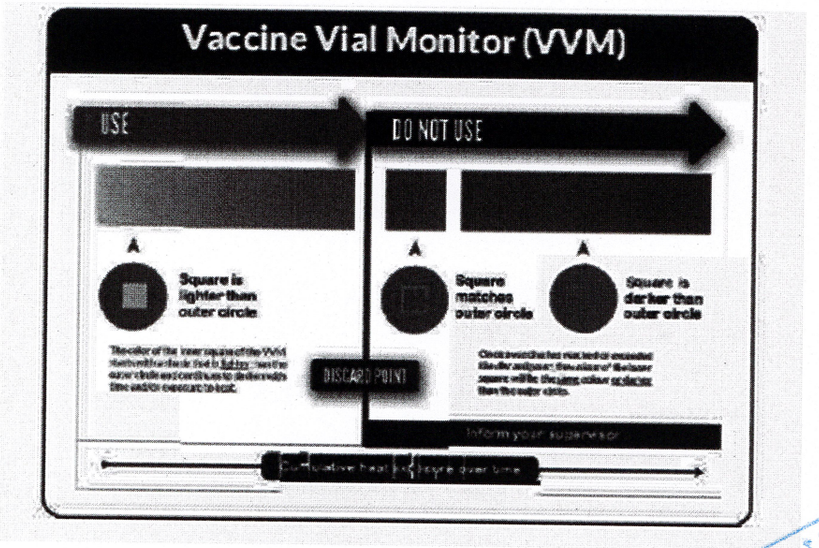
Common: rash erythematous, erythema

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.



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

Issuance date: Jan. 26, 2017
Revised date: Nov. 15, 2019

Manufactured by: LG Chem, [Factory 1]129, Seokam-ro, Iksan-si, Jeollabuk-do, Korea,
[Factory 2] 151, Osongsaengmyeong 1-ro, Osong- eup, Heungdeok-gu,Cheongju-si, Chungcheongbuk-do, Korea.