APPROVED PACKAGE INSERT

SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

EUVAX B INJ – Solution for Intramuscular Injection

COMPOSITION:

Each 1,0 ml contains:

Purified HBs Antigen (KRTB)……20,0 µg

Aluminium Hydroxide Gel (as Aluminium)…….. 0,5 mg

Potassium Phosphate Monobasic…… q.s. (≈ 1,0 mg)

Sodium Phosphate Dibasic…… q.s. (≈ 0,8 mg)

Sodium Chloride…… 8,5 mg

Distilled Water for Injection……. q.s.

PHARMACOLOGICAL CLASSIFICATION:

A 30.1 Biologicals – Antigen

PHARMACOLOGICAL ACTION:

EUVAX B INJ is a Hepatitis B surface antigen preparation using recombinant DNA technology. The surface antigen is synthesized in yeast cells and can be used as a vaccine against hepatitis B. The purified surface antigens contain all of the major molecular antigens (Pre-S1, Pre-S2 and sAg) that have been recognized to be important in including natural immunity against the hepatitis B virus.

INDICATIONS:

EUVAX B INJ is indicated for active immunisation against Hepatitis B virus.

CONTRA-INDICATIONS:

Persons with hypersensitivity to yeast or any other component of the vaccine.

Pregnancy: Safety of this vaccine during pregnancy has not been established.

Efficacy in immunocompromised or immunosuppressed subject has not been established.

WARNINGS:

EUVAX B INJ should be used with caution in patients with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Care should be taken with nursing mothers.

Epinephrine should be available for use in case of anaphylaxis or severe anaphylactoid reaction. Treatment of adverse effects is symptomatic and supportive.

Because of the long incubation period for Hepatitis B, it is possible for unrecognized infection to be present at the time when EUVAX B INJ is given. EUVAX B INJ may not prevent hepatitis B in such patients.

Any serious active infection is reason for delaying the use of EUVAX B INJ, except in cases where, in the opinion of the physician, withholding the vaccine may entail an even greater risk.

EUVAX B INJ must not be injected intravenously or intradermally.

INTERACTIONS:

There are no known interactions.

PREGNANCY AND LACTATION:

The safety of this vaccine during pregnancy has not been established. Pregnant women should not receive this vaccine, and care should be taken with nursing mothers.

DOSAGE AND DIRECTIONS FOR USE

EUVAX B INJ is for intramuscular use only. Do not inject intravenously.

Neonates and children 10 years old or younger:…….0,5 ml (10 µg)

Adults and children over 10 years:……..1,0 ml (20 µg)

The basic immunization schedule consists of 3 intramuscular injections.

1st dose: at elected date (6 weeks of age for neonates)

2nd dose: 1 month later

3rd dose: 6 months after 1st dose

Alternate Schedule:

The alternate schedule is indicated for high-risk groups such as neonates born of hepatitis B infected mothers, others who have or might have been recently exposed to the virus e.g. health care personnel or any other personnel who have direct contact with patients or their body fluid; patients requiring haemodialysis; haemophiliacs and those receiving regular blood transfusions or blood products.

Persons at high-risk of contracting hepatitis B also include contacts or sexual partners of cases or carriers of hepatitis B, individuals who frequently change sexual partners, parenteral drug abusers and travelers to high-risk areas.

1st dose: at elected date

2nd dose: 1 month later

3rd dose: 2 months after 1st dose

Site of injection:

Adults: The deltoid muscle of the upper arm

Infants: The anterolateral area of the thigh

Shake the vial well before administration since a fine white deposit with a clear colourless supernatant may form on storage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Common (≥ 1/100,<1/10)

Local reactions

Erythema, pain, swelling, warmth or induration. These generally disappear within 48 hours.

Systemic reactions:

Malaise, weakness, fatigue, headache, nausea, vomiting, fever, dizziness, myalgia or arthralgia.

Uncommon (≥1/1 000, <1/100)

Guillain-Barré syndrome, neuropathy including hypoesthesia or severe nervous system disorder.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Refer to “Side Effect and Special Precautions”. Treatment is symptomatic and supportive.

IDENTIFICATION:

Slightly opaque, well dispersed, white suspension in clear, colourless vial.

PRESENTATION:

0,5 ml/vial: Packs containing 1, 10 or 20 clear, colourless vials.

1,0 ml/vial: Packs containing 1, 10 or 20 clear, colourless vials.

STORAGE INSTRUCTIONS:

Store at 2 to 8 °C. DO NOT FREEZE.

Opened vials of EUVAX B INJ may be used in subsequent immunization sessions provided that:

a. The vaccine expiry date has not passed.

b. The vaccine is stored at 2 to 8°C

c. The vaccine is not removed from the Health Centre for immunization activities.

d. The content of the opened multidose vial is discarded one month after the first broaching

However, if sterile procedures have not been fully observed or there is suspicion that an open vial of vaccine has been contaminated, it must be discarded immediately.

Shake well before using. Thorough agitation at the time of administration is necessary to maintain a uniform suspension of the vaccine.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

35/30.1/0024

NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Specpharm (Pty) Ltd

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