

APPROVED PATIENT INFORMATION LEAFLET

Patient Information Leaflet for Euvax B Inj

Read this leaflet carefully before this medicine is administered.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

EUVAX B INJ – Solution for Intramuscular Injection

WHAT EUVAX B INJ CONTAINS

Each 1,0 ml contains 20,0 µg Purified HBs Antigen (KRTB)

It also contains the following ingredients: Aluminium Hydroxide Gel, Potassium Phosphate Monobasic, Sodium Phosphate Dibasic, Sodium Chloride, and Distilled Water for Injection.

WHAT EUVAX B INJ IS USED FOR

EUVAX B INJ is used for the prevention of hepatitis B infection. It is a vaccine and works by stimulating the body to produce antibodies against hepatitis B infection.

BEFORE USING EUVAX B INJ

Do not use Euvax B Inj

- if you are hypersensitive (allergic) to Purified HBs Antigen (KRTB) or any of the other ingredients of Euvax B Inj, including yeast and mercury
- if you have had an allergic reaction to a hepatitis B vaccine in the past
- if you are pregnant
- if you have a weakened immune system, have an illness that may affect your immune system or are on immunosuppressive therapy.

Take special care with Euvax B Inj

- if you have a heart or lung disease
- if you suffer from any illness where fever or a systemic reaction could pose a significant risk
- if you are a nursing mother
- if you are suffering from fever or an infection.

Because of the long incubation period for Hepatitis B, it is possible for unrecognised infection to be present at the time when EUVAX B INJ is given.

EUVAX B INJ may not prevent hepatitis B in such patients.

HOW TO USE EUVAX B INJ

EUVAX B INJ should be injected in the muscle only. It must NOT be injected into the skin or into a vein.

New-born babies 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 immunisation schedule consists of 3 injections into the muscle:

1st injection: now (6 weeks of age for new-born babies)

2nd injection: 1 month later

3rd injection: 6 months after 1st injection

An alternate immunisation schedule may be used for certain high risk groups such as new-born babies 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.

The alternate immunisation schedule consists of 3 injections into the muscle:

- 1st injection: now
- 2nd injection: 1 month later
- 3rd injection: 2 months after 1st dose

The injection should be given in the following places:

- Adults: The muscle of the upper arm
- Infants: The thigh muscle

Your doctor or nurse will shake the vaccine well before it is used and it should not be used if it appears discoloured or clumped.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

Please return for your injections at the recommended times. If you miss a dose of Euvax B Inj, contact your doctor immediately.

POSSIBLE SIDE-EFFECTS:

All medicines may cause unwanted effects.

Seek medical attention right away if a severe allergic reaction (rash; hives; difficulty in breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue) occurs.

Check with your doctor, pharmacist or healthcare professional if any of these common unwanted effects persist or become bothersome:

Redness, pain, swelling, warmth or hardness at the injection site. These generally disappear within 48 hours.

General feeling of discomfort, weakness, tiredness, headache, nausea, vomiting, fever, dizziness, pain or tenderness of the muscles and pain in the joints.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Store at 2 to 8 °C (in a refrigerator). DO NOT FREEZE.

Opened vials of EUVAX B INJ may be used in subsequent immunisation 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 immunisation activities.
- d. The content of the opened multidose vial is discarded one month after 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.

Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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.

IDENTIFICATION OF EUVAX B INJ

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

REGISTRATION NUMBER: 35/30.1/0024

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

Specpharm (Pty) Ltd
Cnr 15th and Pharmaceutical Road
Halfway House
Midrand
South Africa

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

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