

PATIENT INFORMATION LEAFLET

BIEMPARIN 25000 IU/5 ml vial containing solution for I.V., S.C. injection

Applied intravenously or subcutaneously.

- **Drug substance:** Each 5 ml of vial contains 25000 IU of heparin sodium.
- **Excipient(s):** Benzyl alcohol, sodium chloride, water for injections and sodium hydroxide or hydrochloric acid for adjustment of acidity.

Read all of this LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this drug, tell your doctor that you are using this medication when you go to the doctor or hospital.*
- *Please keep strictly to write in these instructions. Do not use high or low dose outside the recommended dose of drug.*

In this leaflet:

- 1. What BIEMPARIN is and what it is used for?*
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1. WHAT BIEMPARIN IS AND WHAT IT IS USED FOR?

BIEMPARIN belongs to a group of anticoagulant medicines named as heparin sodium.

BIEMPARIN vial contains a colorless, clear solution of heparin sodium. The box contains one vial.

BIEMPARIN is standardized heparin.

Heparin sodium prevents your blood clots. It provides that your blood stream continues smoothly. The tubes that carry blood around your body are called arteries and veins.

BIEMPARIN is used for following indications:

- to prevent further development of harmful blood clots in your veins (arteries and veins) (therapeutic purpose)
- to help stop harmful blood clots in your veins (arteries and veins) growing bigger (preventive purpose)
- in hemodialysis and heart surgery
- in heart attack or if there is a risk of heart attack
- in various blood clotting disorders

Blood clots may occur in your leg (deep vein thrombosis or DVT for short), the veins that carry blood to the lungs (pulmonary embolism) in your body. The risk of clot formation increase, if you are overweight, pregnant, have certain blood disorders or have already had a pulmonary embolism, DVT, heart attack or stroke or do not move around for long periods of time. 2.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BIEMPARIN?

If you are having an epidural or spinal anaesthetic, you must remind your doctor that you are having heparin infusion before you receive any anaesthetic. If you are pregnant, please tell your doctor.

You should inform your anesthetist (including your dentist) that you are taking BIEMPARIN when you will undergo a planned surgery.

After you have the anaesthetic your doctor or nurse will make regular checks. This is to check if you are getting any major bleeding or bruising around your spine.

This may cause paralysis that could be permanent. Any signs this may be happening to you include tingling, weakness or numbness in your legs or body, back pain or problems in going to the toilet. This happens very rarely.

After you have the anaesthetic your doctor will tell you when you can take your medicine again.

DO NOT USE BIEMPARIN in the following conditions:

- If you are allergic to the drug substance of the product (heparin sodium), or any of the other ingredients of this product (benzyl alcohol)
- If you have, or have ever had, a big drop in the clotting cells (platelets) in your blood, caused by having any type of heparin (reaction called heparin-induced thrombocytopenia).
- If you have any condition which makes you bleed severely, such as haemophilia.
- If you have hypertension
- If you have severe liver problems.
- If you have a stomach ulcer.

- If you have known endocarditis (an inflammation of the lining of the heart and heart valves).
- If you have had a brain haemorrhage
- If you have an injury to your spine, head, eyes or ears.
- If you have recently had, or are about to have an operation involving your spine, head, eyes or ears.
- If you may be having a miscarriage.

Heparin sodium should not be applied to you.

This product must not be given to premature or newborn babies or babies up to 1 month of age.

Take special care with BIEMPARIN in the following conditions:

- If you are allergic (hypersensitive) to low molecular weight heparins, such as tinzaparin, enoxaparin or dalteparin.
- If you have kidney problems.
- If you have liver problems.
- If you have a disease related to your eyes (retina)
- If you have problems with your blood pressure (hypertension).
- If you have known diabetes mellitus.
- If you had a lumbar puncture before
- If you have a condition called metabolic acidosis.
- If you have any medical condition which may cause high levels of potassium in your blood (hyperkalaemia), ask your doctor if you are unsure.
- If you are taking a medicine from the group called potassium-sparing diuretics, such as amiloride or spironolactone.
- If you have any condition which makes you more likely to bleed more easily.
- If this medicine is used for a child who is between one and three years old, please ask your doctor.
- If you are taking another medicine that may affect your blood clotting. For a list of these medicines see the section “Taking other medicines”.
- If you are pregnant or you think pregnancy.

Please read “Important information about some of the ingredients of BIEMPARIN” in this leaflet.

Your doctor may take a blood test before you start having BIEMPARIN, and while you are having it. This is so the doctor can check you are having the right dose. These tests are also to check the level of the clotting cells (platelets) and potassium in your blood.

This medicine may make you bleed more easily. The doctor or nurse should take care when giving you any other injections or procedures.

If you suffer from, or have in the past suffered from, talk to your doctor.

Using of BIEMPARIN with food and drink

Heparin should not be taken with alcohol.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

If it is required, your doctor may apply heparin to you during pregnancy. Epidural anesthesia should not be applied particularly during childbirth after the use.

Please consult your doctor immediately if you notice that you are pregnant during treatment.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

It is possible to breast-feeding while using this medicine.

Driving and using machines

Usually BIEMPARIN may have little effect on your ability to drive or use machines. However, you should check with your doctor if you feel any side effect that may stop you from driving or using machines.

Important information about some of the ingredients of BIEMPARIN

This medicinal product contains less than 1 mmol (23 mg) of sodium per dose; that is, it does not actually contain sodium.

BIEMPARIN contains benzyl alcohol (9,45 mg/ml) as preservative. Care should be taken when prescribing for suspicious patient. It must not be given to premature or newborn babies.

It may cause toxic and allergic reactions in babies and the children up to 3 years of age.

If you are pregnant, your doctor decide receiving this medicine.

Using other medicines

- If you use angiotensin converting enzyme inhibitors or angiotensin II antagonists such as enalapril, losartan or valsartan for treating high blood pressure or heart, the amount of potassium in your blood can become too high (hypercalcemia).
- If you use non-steroidal anti-inflammatory drugs, such as ibuprofen or diclofenac for arthritis or aches or pains, you may be likely to bleed more easily.
- If you use salicylates, such as aspirin for reducing pain and inflammation or for stopping harmful blood clots forming, you may be likely to bleed more easily.
- If you use platelet aggregation inhibitors, such as clopidogrel for stopping harmful blood clots forming, you may be likely to bleed more easily.
- If you use thrombolytic agents such as streptokinase for dissolving blood clots, you may be likely to bleed more easily.

- If you use vitamin K antagonists such as warfarin for stopping harmful blood clots, you may be likely to bleed more easily.
- If you use glyceryl trinitrate infusion for treating angina, this may reduce the effect of Heparin infusion.
- Activated protein C: for getting rid of blood clots. You may be likely to bleed more easily.
- If you use dextrans for increasing your blood volume., you may be likely to bleed more easily.

Your doctor may carry out check-ups on you, including blood tests, if you take any of these medicines at the same time with Heparin.

Please tell your doctor or pharmacist if you are using or have recently used any other medicine, including medicines obtained without a prescription.

3. HOW TO USE BIEMPARIN

Appropriate usage and dose/frequency of application instructions:

The heparin concentration in BIEMPARIN is 5000 IU/ml. Dose of heparin is defined as IU whereas all heparin preparations don't contain the same concentration.

BIEMPARIN will be applied to you by a doctor or nurse.

Your doctor will decide the dose of the drug depending on your disease and will prescribe.

BIEMPARIN should not be injected by mixed with any other injection.

Method of administration

It is applied intravenously or subcutaneously.

Different age groups:

Children:

BIEMPARIN should not be used in the babies up to 1 month old.

Elderly:

It is recommended the dosage reduction and monitoring of APTT.

Special uses:

Kidney and liver failure:

If you have renal or hepatic insufficiency, your doctor can decide that you should take a lower dose of BIEMPARIN.

If you have the impression that the effect of BIEMPARIN is too strong or too weak, talk to your doctor or pharmacist.

If you use more BIEMPARIN than you should:

It is not expected that you use BIEMPARIN than you should, because it is applied by your doctor or nurse.

If you think too much medicine has been given to you, contact your doctor or nurse.

You may start to haemorrhage (bleed severely) (Please see section 4).

You may be given another injection of a medicine called protamine sulphate.

If you use more BIEMPARIN than you should, talk your doctor or pharmacist.

If you forget to use BIEMPARIN:

It is not expected that you use BIEMPARIN than you should, because it is applied by your doctor or nurse.

If you think that you have missed a dose, tell your doctor or nurse.

If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, BIEMPARIN can cause side effects in people who are sensitive to its ingredients.

Stop the use of BIEMPARIN and contact your doctor or hospital immediately if you experience any of the following symptoms:

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash
- Your skin develops blisters at the site of your injection.

These are all very serious side effects.

If you experience any of these symptoms, it means that you are severe allergic to BIEMPARIN. Urgent medical attention or hospitalization may be required.

You must get urgent medical help if you have any of the following symptoms after having an epidural or spinal anaesthetic. You may be developing paralysis:

- Tingling, weakness or numbness in your legs or lower body
- Back pain
- Problems in going to the toilet.

You should tell your doctor straight away if you spot any of the following signs which mean you may be starting to bleed severely:

- Red or brown urine
- Black tarry stools
- Unusual bruising
- Bleeding from your nose, mouth or any operation wound that will not stop.

Other possible side effects:

Very common side effects (probably affect up to 1 in 10 people)

- Bruising at the site of the injection.
- Irritation at the site of the injection.
- Bleeding (haemorrhage). This may be more likely if you are taking a high dose of Heparin infusion.
- Changes in your blood test results.

Common side effects (probably affect less than 1 in 100 people)

- Rash.
- Itchy raised rash (urticaria).
- Reduction of bone density (osteoporosis). The bones become less strong and can break more easily in patients taking heparin for a long time.

Uncommon side effects (probably affect less than 1 in 1,000 people)

- Bruising or bleeding more easily. Your blood may also form more harmful clots. A big drop in clotting cells (platelets) in your blood may give you these symptoms. Your doctor can explain this more.

Very rare side effects (probably affect less than 1 in 10,000 people)

- Prolonged, painful erections in men.

If you have experience any side effect stating above, please tell your doctor. Some of these side effects can be serious.

If you experience any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE BİEMPARİN

Keep BİEMPARİN in a safe place out of the sight and reach of children and keep in packing. Store in the original package and at room temperature under 25°C.

Please note that the solution is clear and the packaging is not opened before the application.

The product should not be used after the expiry date.

Do not use BİEMPARİN after the expiry date on the packaging

If you notice defects on product and/or packaging, do not use BİEMPARİN.

Marketing Authorisation Holder: BİEM İLAÇ SANAYİ ve TİC. A.Ş.

Turgut Reis Cad., No: 21, 06570, Tandoğan Çankaya/Ankara

Tel: +90 312 230 29 29

Faks: +90 312 230 68 00

Manufacturer: Mefar İlaç Sanayii A.Ş.

Ramazanoğlu Mah. Ensar Cad. No:20 Kurtköy-Pendik TR 34906

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