HIBOR®

(Bemiparin Sodium)

ACTION

HIBOR (Bemiparin sodium) belongs to a group of medicines called anticoagulants, which help to prevent blood from clotting in the blood vessels.

HIBOR is a second-generation low molecular weight heparin (LMWH). It has a very low mean molecular weight (3600 Dalton), a long half life (5.3 hrs) and a large anti Xa: anti IIa ratio (8:1).

INDICATIONS

Hibor is indicated in the following cases:

- To prevent blood clots in the veins after general abdominal surgery in patients with a moderate risk of venous thromboembolism.
- Prevention of the thromboembolic disease in non-surgical patients
- Prevention of clotting in the extracorporeal circuit during haemodialysis
- To prevent blood clots in the veins after a major orthopaedic surgery in patients with high risk venous thromboembolsim.
- Secondary prevention of venous thromboembolism recurrence in patients with deep vein thrombosis and transient high-risk
- Treatment of deep vein thrombosis

DOSAGE AND ADMINISTRATION

1. To prevent blood clots in the veins after general abdominal surgery in patients with a moderate risk of venous thromboembolism
   - The recommended dose is an injection of Bemiparin 2,500 IU/day administered by subcutaneous injection.
   - Prophylactic treatment should be maintained for at least 7-10 days after the surgical procedure and until the patient is fully mobile or the risk of thrombolic disease has decreased.
   - The initial dose should be administered 2 hours before or 6 hours after surgery
2. Prevention of the thromboembolic disease in non-surgical patients:
   The recommended dose of bemiparin is 2,500 IU/day or 3,500 IU/day by subcutaneous route, according to the set of risk factors of the patients, whether defined as mild or high-risk thromboembolic patients.
   Prophylactic treatment must be continued, according to the physician's criteria, during the risk period or until the complete mobilisation of the patient.
3. Prevention of clotting during haemodialysis:
   When used in haemodialysis, HIBOR 2,500 IU or 3,500 IU is usually administered by injecting one bolus dose (the contents of the syringe) into the arterial side of the dialysis machine.
4. To prevent blood clots in the veins after a major orthopaedic surgery in patients with high risk venous thromboembolsim:
   - The recommended dose is an injection of Bemiparin 3,500 IU/day administered by subcutaneous injection.
   - Prophylactic treatment should be maintained for at least 7-10 days after the surgical procedure and until the patient is fully mobile or the risk of thrombolic disease has decreased.
   - The initial dose should be administered 2 hours before or 6 hours after surgery.
5. Secondary prevention of venous thromboembolism recurrence in patients with deep vein thrombosis and transient high-risk:
   HIBOR can be administered at a fixed dose of 3,500 IU/day (up to a maximum of 3 months) in patients who have received anticoagulant treatment for deep vein thrombosis with or without pulmonary embolism, as therapeutic alternative to the administration of oral anticoagulants or whenever they are contraindicated.
6. Treatment of deep vein thrombosis

Adults:

As a general rule, HIBOR 5,000 IU, 7,500 IU or 10,000 IU should be administered by subcutaneous injection at the dose of 115 IU/kg/day, once daily, for 7 ± 2 days. This regimen corresponds -depending on the body weight- to the following ranges:

Body Weight	Dosage
< 50 kg	0.2ml (5,000 IU)
50 - 70 kg	0.3 ml (7,500 IU)
> 70 kg	0.4ml (10,000 IU)

In patients weighing more than 100 kg body weight, the dose should be adjusted depending on the weight, at a level of 115 IU/kg/day

Usually oral anticoagulants will be commenced 3-5 days after the first administration of HIBOR 5,000 IU, 7,500 IU or 10,000 IU, and the dose will be adjusted so as to keep a blood test level called the INR value between 2-3 times the control value. Oral anticoagulation is usually continued for at least of 3 months.

Injection technique

- The pre-filled syringes are ready for use and must not be purged before the subcutaneous injection.
- The injection should be given into the subcutaneous tissue of the waist, alternatively on the left and right sides. The needle should be completely introduced perpendicularly but not tangentially, into the thick part of a skin fold held between the thumb and the forefinger; the skin fold should be maintained throughout the whole injection. Do not rub the injection site after administration.
- HIBOR must not be injected into the muscle nor mixed with any other injection.
- HIBOR is usually administered by a doctor or a nurse by subcutaneous injection .It is usually given once a day.

CONTRAINDICATIONS

HIBOR must not be used in the following situations:

- In patients who have allergic reaction after being given any medicine containing bemiparin sodium or heparin.
- In patients with a history of heparin-induced thrombocytopaenia (HIT).
- In patients suffering from any condition which results in tendency to bleed excessively.
- In patients suffering from serious liver and/or pancreas disease.
- In patients with disseminated Intravascular Coagulation (DIC) attributable to a heparin-induced decrease in the number of platelets.
- In case of bacterial Endocarditis.
- In patients with active major bleeding (e.g. active stomach ulcer, stroke, brain tumours, or if you have suffered from a brain haemorrhage).
- In patients having an injury to or are about to have an operation in the brain, spine, eyes and/or ears.
- Epidural or spinal anaesthesia during surgery are contra-indicated if the patient is treated with HIBOR 5,000 IU/7,500 IU/10,000 IU

WARNINGS

Low molecular weight heparins should not be used interchangeably since they differ in their manufacturing process, molecular weights, specific anti-Xa activities, units and dosage. Very careful attention and compliance with specific instructions on use of each product are absolutely essential.

Do not administer by intramuscular route

In case of Epidural anesthesia, Hibor 2,500 IU or 3,500 IU should be initiated 4 hours after removal of the catheter. The next dose should be given after completion of the surgery.

Children: The use of HIBOR is not recommended in children.

Elderly: The same dosage should be used for elderly people as for any other adults.

Renal and hepatic impairment: There are insufficient data to recommend a different dose of HIBOR in this group of patients.

Pregnancy and lactation: There is not enough experience with HIBOR to recommend usage in pregnant or lactating women.

PRECAUTIONS

Caution should be exercised in patients with liver or renal failure uncontrolled high blood pressure, a history of gastroduodenal ulcer disease, thrombocytopenia or other conditions with an increased risk of bleeding or in patients undergoing spinal or epidural anaesthesia and/or lumbar puncture

Driving and using machines:

Bemiparin has no effect on the ability to drive and use precision or dangerous machinery

Drug interactions

The concomitant administration of Bemiparin and oral anticoagulants, non-steroidal anti-inflammatory drugs, glycoprotein IIb/IIIa receptor antagonists, systemic glucocorticoids or dextran will increase the risk of bleeding. If combination cannot be avoided, it should be used under careful clinical and laboratory monitoring.

SIDE EFFECTS

- Bleeding: this may occur during the treatment of anticoagulant in the presence of associated risk factors.
- Thrombocytopenia: In rare cases, there may be a decrease in the number of platelets.
- Patients may develop bruises (violet marks) at injection sites, Local reactions: Rarely, mild skin allergic reactions (skin rash, itching) may occur.
  Very rarely, serious allergic reactions may occur (fever, difficulty in breathing, skin itching, redness, sickness, nausea, vomiting).
- Very rarely, administration of anticoagulants accompanied by epidural or spinal anaesthesia, may result in bleeding in the spinal area. This may damage the nerves leading to a loss of strength or loss of sensation in legs or lower body
- Others: A symptomatic and reversible increases of liver enzymes in blood (transaminases).

OVERDOSAGE

Accidental overdosage after extracorporeal or subcutaneous administration of massive dose of Bemiparin sodium may lead to bleeding complications. Neutralization can be obtained by slow intravenous of a suitable dose of protamine sulphate.

PRESENTATIONS

Pre-filled syringes, "pack of 2"

HIBOR 2,500 IU :	Bemiparin sodium 2,500 IU anti-Xa.
HIBOR 3,500 IU :	Bemiparin sodium 3,500 IU anti-Xa.
HIBOR 5,000 IU :	Bemiparin sodium 5,000 IU anti-Xa.
HIBOR 7,500 IU :	Bemiparin sodium 7,500 IU anti-Xa.
HIBOR 10,000 IU :	Bemiparin sodium 10,000 IU anti-Xa.

Manufactured by:
Laboratorios Farmacéuticos Rovi, S.A.

For
HIKMA Pharmaceuticals, Amman-Jordan

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Keep medicament out of the reach of children

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