RENAL CARE FRANCHISE

UNIHEPA

Heparin Sodium BP 5000IU/ml Injection (5ml Vial)

Experience a Clot Free Journey

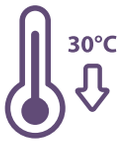
MS2424
5 005-03/2006

INDICATIONS

- Prophylaxis and treatment of venous thrombosis and pulmonary embolism
- Treatment of myocardial infarction and arterial embolism
- Prevention of clotting in arterial and heart surgery
- Prevention of cerebral thrombosis
- Anticoagulant in blood transfusions, extracorporeal circulation, dialysis procedures, and for laboratory purposes

MS2424
5 005-03/2006

STORAGE CONDITION



Store below 30°C

Protect from light

Protect from freezing

- A vial can be stored for up to 28 days at 30°C following first withdrawal, provided the solution withdrawn with strict aseptic technique

Abbreviated Prescribing Information

Composition: Each ml contains: Heparin Sodium BP (Bovine Mucosa) 5000 IU. Preservative: Benzyl Alcohol 1.0% w/v. **Indications:** Heparin is indicated for prophylaxis and treatment of venous thrombosis and pulmonary embolism; in the treatment of myocardial infarction and arterial embolism; for prevention of clotting in arterial and heart surgery and for prevention of cerebral thrombosis. Heparin may also be used as an anticoagulant in blood transfusions, extracorporeal circulation, dialysis procedures, and for laboratory purposes. **Dosage:** Intravenous administration: 5,000 - 10,000 IU every 4 hours or 500 IU/kg bodyweight daily as a continuous infusion in sodium chloride injection or dextrose injection. Doses should be individually adjusted according to coagulation tests. Subcutaneous administration: The initial dose is 250 IU/kg bodyweight. Further doses should be given every 12 hours and individually adjusted according to coagulation tests. Dosage adjustment: It is recommended that dosages be adjusted to maintain a thrombin clotting time, whole blood clotting time or activated partial thromboplastin time 1.5 to 2 times that of control on blood withdrawn 4 - 6 hours after the first injection or commencement of infusion and at similar intervals until the patient is stabilised. Prophylactic Dosage: Administration is by subcutaneous injection. Patients undergoing major elective surgery: 5,000 IU should be given 2 hours pre-operatively and then every 8 - 12 hours post-operatively for 10 - 14 days or until the patient is ambulant, whichever is the longer. Following myocardial infarction: 5,000 IU should be given twice daily for 10 days or until the patient is mobile. Other patients: 5,000 IU should be given every 8 - 12 hours. These standard prophylactic regimens do not require routine control. **Contraindications:** Heparin therapy is contra-indicated in patients who are hypersensitive to the drug. It should not be used in the presence of actual or potential haemorrhagic states, eg. haemophilia, ascorbic acid deficiency or increased capillary fragility; threatened abortion; immediate postpartum period, subacute bacterial endocarditis; severe hypertension; gastric or duodenal ulcers; advanced renal or hepatic disease; during and immediately after spinal or major surgery, especially those involving the brain, eye or spinal cord. **Special Precautions:** Heparin therapy should be given with caution to patients with impaired renal or hepatic function, or hypersensitivity to low molecular weight heparins. Heparin can suppress adrenal secretion of aldosterone leading to hyperkalaemia, particularly in patients such as those with diabetes mellitus, chronic renal failure, pre-existing metabolic acidosis, a raised plasma potassium or taking potassium sparing drugs. The risk of hyperkalaemia appears to increase with duration of therapy but is usually reversible. Plasma potassium should be measured in patients at risk before starting heparin therapy and monitored regularly thereafter particularly if treatment is prolonged beyond about 7 days. In patients undergoing peridural or spinal anaesthesia or spinal puncture, the prophylactic use of heparin may be very rarely associated with epidural or spinal haematoma resulting in prolonged or permanent paralysis. The risk is increased by the use of a peridural or spinal catheter for anaesthesia, by the concomitant use of drugs affecting haemostasis such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors or anticoagulants, and by traumatic or repeated puncture. In decision making on the interval between the last administration of heparin at prophylactic doses and the placement or removal of a peridural or spinal catheter, the product characteristics and the patient profile should be taken into account. Subsequent dose should not take place before at least four hours have elapsed. Re-administration should be delayed until the surgical procedure is completed. Should a physician decide to administer anti-coagulation in the context of peridural or spinal anaesthesia, extreme vigilance and frequent monitoring must be exercised to detect any signs and symptoms of neurologic impairment, such as back pain, sensory and motor deficits and bowel or bladder dysfunction. Patients should be instructed to inform immediately a nurse or a clinician if they experience any of these. As there is a risk of antibody-mediated heparin-induced thrombocytopenia, platelet counts should be measured in patients receiving heparin treatment for longer than 5 days and the treatment should be stopped immediately in those who develop thrombocytopenia. **Adverse Reactions:** Haemorrhage is the major risk of heparin therapy and may range from minor local ecchymoses to major haemorrhagic complications. Delayed onset thrombocytopenia is also a possible complication of heparin therapy. If this occurs, the drug should be withdrawn immediately. Skin necrosis has infrequently been reported at injection sites. It is thought to be a localised manifestation of heparin induced platelet aggregation and thrombosis and should be taken as a warning sign in patients who develop it. Heparin should be discontinued immediately. Allergic reactions to heparin occur rarely. Hypersensitivity may be manifested by pruritus, urticaria, asthma-like symptoms and anaphylactoid reactions. Osteoporosis complicated by spontaneous bone fracture has been reported with prolonged use of large doses of heparin. Transient alopecia and diarrhea may occur. Heparin products can cause hypoaldosteronism which may result in an increase in plasma potassium.

References

1. Unihepa product information leaflet. Data on file. Duopharma Marketing Sdn Bhd.

All adverse events should be reported to PV@duopharmabiotech.com
Full prescribing information is available upon request.
For Healthcare Professionals Only.

Please contact us for further information.

Duopharma Marketing Sdn. Bhd.
Registration No: 197601001745 (27754-W)
Lot No. 2,4,6,8 & 10, Jalan P/7, Seksyen 13, Kawasan Perusahaan,
43650 Bandar Baru Bangi, Selangor. Tel: 603-8924 2188 Fax: 603-8925 7930

UNIHEPA-5000/BRC/202308/01