120 x 120 mm (Front & Back)

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

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Heparin Sodium Injection IP 5000 IU/5ml

HEPAXARIN™-5000

For I.V. / S.C. Use Only

Composition :
Each ml contains :

Heparin Sodium	IP	1,000 IU
Water for Injections	IP	q.s.

3. Dosage Form and Strength

Heparin is supplied in a glass vial containing injection for infusion, equivalent to heparin sodium 5000 IU/5ml and 25000 IU/5ml.

4 Clinical particulars

4.1 Therapeutic indications

•Prophylaxis and treatment of venous thrombosis and pulmonary embolism

•Prophylaxis and treatment of the thromboembolic complications associated with atrial fibrillation

•Treatment of acute and chronic consumption coagulopathies

•Prevention of clotting in arterial and cardiac surgery

•Prophylaxis and treatment of peripheral arterial embolism

•Anticoagulant use in transfusion, extracorporeal circulation, and dialysis procedures

4.2 Posology and Method of Administration

Posology

Recommended Adult Dosages:

*Based on 68 kg patient. Adjust dose based on laboratory monitoring.

Therapeutic Anticoagulant Effect with Full-Dose Heparin*		
Deep Subcutaneous (intrafat) injection *Use a different site for each injection*	Initial Dose	333 units/kg of a concentrated solution subcutaneously
	Every 12 hours	250 units/kg of a concentrated solution subcutaneously
Intermittent Intravenous injection	Initial Dose	10,000 units, either undiluted or in 50 to 100 ml of 0.9% sodium chloride injection IP
	Every 4 to 6 hours	5,000 units to 10,000 units, either undiluted or in 50 to 100 ml of 0.9% sodium chloride injection, IP.
Continuous Intravenous Infusion	Initial Dose	5,000 units by intravenous injection
	Continuous	20,000 units/24 hours to 40,000 units/24 hours in 1000 ml of 0.9% sodium chloride injection, IP (or any compatible solution) for infusion.

Cardiovascular Surgery		
Intravascular via Total Body Perfusion	Initial Dose	not less than 150 units/kg; adjust for longer procedures

Low-dose Prophylaxis of Postoperative Thromboembolism		
Deep Subcutaneous (Intrafat) Injection	Initial Dose	5,000 units 2 hours before surgery
	Every 8 to 12 hours	5,000 units

Extracorporeal dialysis	
Intravascular via Extracorporeal Dialysis	25 units/kg to 30 units/kg followed by infusion rate of 1,500 units/hour to 2,000 units/hour.

Paediatric population: Do not use this in neonates and infants. There are no adequate and well controlled studies on heparin use in pediatric patients. Pediatric dosing recommendations are based on clinical experience. In general, the following dosage schedule may be used as a guideline in pediatric patients:

Initial Dose	75 units/kg to 100 units/kg (intravenous bolus over 10 minutes)
Maintenance Dose	Infants: 25 units/kg/hour to 30 units/kg/hour; Infants less than 2 months have the highest requirements (average 28 units/kg/hour)
	Children greater than 1 year of age: 18 units/kg/hour to 20 units/kg/hour; Older children may require less heparin, similar to weight-adjusted adult dosage
Monitoring	Adjust heparin to maintain aPTT of 60 seconds to 85 seconds, assuming this reflects an anti-Factor Xa level of 0.35 to 0.70.

Cardiovascular Surgery

Patients undergoing total body perfusion for open-heart surgery should receive an initial dose of not less than 150 units of heparin sodium per kilogram of body weight. Frequently, a dose of 300 units per kilogram is used for procedures estimated to last less than 60 minutes or 400 units per kilogram for those estimated to last longer than 60 minutes.

Low-Dose Prophylaxis of Postoperative Thromboembolism

The most widely used dosage has been 5,000 units 2 hours before surgery and 5,000 units every 8 to 12 hours thereafter for 7 days or until the patient is fully ambulatory, whichever is longer. Administer the heparin by deep subcutaneous (intrafat, i.e., above the iliac crest or abdominal fat layer, arm, or thigh) injection with a fine (25 to 26-gauge) needle to minimize tissue trauma.

Converting to Warfarin

To ensure continuous anticoagulation when converting from heparin sodium injection to warfarin, continue full heparin therapy for several days until the INR (prothrombin time) has reached a stable therapeutic range. Heparin therapy may then be discontinued without tapering.

Converting to Oral Anticoagulants other than Warfarin

For patients currently receiving intravenous heparin, stop intravenous infusion of heparin sodium immediately after administering the first dose of oral anticoagulant; or for intermittent intravenous administration of heparin sodium, start oral anticoagulant 0 to 2 hours before the time that the next dose of heparin was to have been administered.

Extracorporeal Dialysis

Follow equipment manufacturers' operating directions carefully. A dose of 25 units/kg to 30 units/kg followed by an infusion rate of 1,500 units/hour to 2,000 units/hour is suggested based on pharmacodynamic data if specific manufacturers' recommendations are not available.

Heparin resistance

Patients with altered heparin responsiveness or heparin resistance may require disproportionately higher doses of heparin to achieve the desired effect.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Must not be given to premature babies or neonates (contains benzyl alcohol).

Heparin should not be administered by intramuscular injection or after major trauma.

Patients who consume large amounts of alcohol, who are sensitive to the drug, who are actively bleeding or who have haemophilia or other bleeding disorders, severe liver diseases (including oesophageal varices), purpura, severe hypertension, active tuberculosis or increased capillary permeability.

Patients with present or previous thrombocytopenia. The rare occurrence of skin necrosis in patients receiving heparin contra-indicates the further use of heparin either by subcutaneous or intravenous routes because of the risk of thrombocytopenia. Because of the special hazard of post-operative haemorrhage heparin is contra-indicated during surgery of the brain, spinal cord and eye, in procedures at sites where there is a risk of bleeding, in patients that have had recent surgery, and in patients undergoing lumbar puncture or regional anaesthetic block.

The relative risks and benefits of heparin should be carefully assessed in patients with a bleeding tendency or those patients with an actual or potential bleeding site eg. hiatus hernia, peptic ulcer, neoplasm, bacterial endocarditis, retinopathy, bleeding haemorrhoids, suspected intracranial haemorrhage, cerebral thrombosis or threatened abortion.

In patients receiving heparin for treatment rather than prophylaxis, locoregional anaesthesia in elective surgical procedures is contraindicated because use of heparin may be very rarely associated with epidural or spinal haematoma resulting in prolonged or permanent paralysis. If such a procedure is planned the heparin should be stopped and the procedure should be delayed until the aPTT has returned to normal. Epidural anaesthesia use during birth in pregnant women treated with heparin is contraindicated.

Menstruation is not a contra-indication.

Concomitant use of intravenous diclofenac with heparin (including low dose heparin) is contraindicated.

4.4 Special warnings and precautions for use

Hemorrhage

Avoid using heparin in the presence of major bleeding, except when the benefits of heparin therapy outweigh the potential risks.

Hemorrhage, including fatal events, has occurred in patients receiving heparin. Hemorrhage can occur at virtually any site in patients receiving heparin. Adrenal hemorrhage with resultant acute adrenal insufficiency), ovarian hemorrhage, and retroperitoneal hemorrhage have occurred during anticoagulant therapy with heparin. A higher incidence of bleeding has been reported in patients, particularly women, over 60 years of age. An unexplained fall in hematocrit or fall in blood pressure should lead to serious consideration of a hemorrhagic event.

Use heparin sodium with caution in disease states in which there is increased risk of hemorrhage, including:

- Cardiovascular – Subacute bacterial endocarditis, severe hypertension.
- Surgical – During and immediately following: (a) spinal puncture or spinal anesthesia or (b) major surgery, especially involving the brain, spinal cord, or eye.
- Hematologic – Conditions associated with increased bleeding tendencies, such as hemophilia, thrombocytopenia, and some vascular purpuras.
- Patients with hereditary antithrombin III deficiency receiving concurrent antithrombin III therapy – The anticoagulant effect of heparin is enhanced by concurrent treatment with antithrombin III (human) in patients with hereditary antithrombin III deficiency. To reduce the risk of bleeding, reduce the heparin dose during concomitant treatment with antithrombin III (human).
- Gastrointestinal – Ulcerative lesions, continuous tube drainage of the stomach or small intestine, and clinical settings in which stress-induced gastrointestinal hemorrhage is possible.
- Other – Menstruation, liver disease with impaired hemostasis, severe renal disease, or in patients with indwelling catheters.

Heparin-Induced Thrombocytopenia and Heparin-Induced Thrombocytopenia and Thrombosis

Heparin-induced thrombocytopenia (HIT) is a serious antibody-mediated reaction resulting from irreversible aggregation of platelets. HIT occurs in patients treated with heparin and is due to the development of antibodies to a platelet Factor 4-heparin complex that induce in vivo platelet aggregation. HIT may progress to the development of venous and arterial thromboses, a condition known as heparin-induced thrombocytopenia and thrombosis (HITT).

Thrombotic events may also be the initial presentation for HITT. These serious thromboembolic events include deep vein thrombosis, pulmonary embolism, cerebral vein thrombosis, limb ischemia, stroke, myocardial infarction, mesenteric thrombosis, renal arterial thrombosis, skin necrosis, gangrene of the extremities that may lead to amputation, and possibly death.

Monitor thrombocytopenia of any degree closely. If the platelet count falls below 100,000/mm³ or if recurrent thrombosis develops, promptly discontinue heparin, evaluate for HIT and HITT, and, if necessary, administer an alternative anticoagulant. HIT and HITT can occur up to several weeks after the discontinuation of heparin therapy. Patients presenting with thrombocytopenia or thrombosis after discontinuation of heparin should be evaluated for HIT and HITT.

Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preservative

Serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and low-birth weight infants treated with benzyl alcohol-preserved formulation in intravenous solutions, including heparin sodium injection. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations.

When prescribing heparin sodium injection in infants consider the combined daily metabolic load of benzyl alcohol from all sources including heparin sodium injection and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which toxicity may occur is not known.

Thrombocytopenia

Thrombocytopenia in patients receiving heparin has been reported at frequencies up to 30%. It can occur 2 to 20 days (average 5 to 9) following the onset of heparin therapy. Obtain platelet counts before and periodically during heparin therapy. Monitor thrombocytopenia of any degree closely. If the count falls below 100,000/mm³ or if recurrent thrombosis develops, promptly discontinue heparin, evaluate for HIT and HITT, and, if necessary, administer an alternative anticoagulant.

Coagulation Testing and Monitoring

When using a full dose heparin regimen, adjust the heparin dose based on frequent blood coagulation tests. If the coagulation test is unduly prolonged or if hemorrhage occurs, discontinue heparin promptly. Periodically monitor platelet counts, hematocrit, and occult blood in stool during the entire course of heparin therapy, regardless of the route of administration.

Heparin Resistance

Resistance to heparin is frequently encountered in fever, thrombosis, thrombophlebitis, infections with thrombosing tendencies, myocardial infarction, cancer, in postsurgical patients, and patients with antithrombin III deficiency. Close monitoring of coagulation tests is recommended in these cases. Adjustment of heparin doses based on anti-Factor Xa levels may be warranted.

Hypersensitivity

Patients with documented hypersensitivity to heparin should be given the drug only in clearly life-threatening situations.

Because heparin sodium injection is derived from animal tissue, it should be used with caution in patients with a history of allergy.

4.5 Interaction with other medicinal products and other forms of interaction

Analgesics: Drugs that interfere with platelet aggregation e.g. aspirin and other NSAIDs should be used with care. Increased risk of haemorrhage with;

- Ketorolac
- Intravenous diclofenac

Avoid concomitant use of either ketorolac or intravenous diclofenac, even with low-dose heparin.

Anticoagulants, platelet inhibitors, etc: Increased risk of bleeding with oral anticoagulants, epoprostenol, clopidogrel, ticlopidine, streptokinase, dipyridamole, dextran solutions, abciximab, eptifibatide or any other drug which may interfere with coagulation.

Heparin sodium may prolong the one-stage prothrombin time. Therefore, when heparin sodium is given with dicumarol or warfarin sodium, a period of at least 5 hours after the last intravenous dose or 24 hours after the last subcutaneous dose should elapse before blood is drawn if a valid prothrombin time is to be obtained.

Cephalosporins: Some cephalosporins, e.g. cefactor, cefixime and ceftriaxone, can affect the coagulation process and may therefore increase the risk of hemorrhage when used concurrently with heparin.

ACE inhibitors, angiotensin-II receptor antagonists or the renin inhibitor aliskiren: Hyperkalaemia may occur with concomitant use.

Nitrates: Reduced activity of heparin has been reported with simultaneous intravenous glyceryl trinitrate infusion.

Probenecid: May increase the anticoagulant effects of heparin.

Tobacco smoke: Nicotine may partially counteract the anticoagulant effect of heparin. Increased heparin dosage may be required in smokers.

Interference with diagnostic tests may be associated with pseudo-hypocalcaemia (in haemodialysis patients), artefactual increases in total thyroxine and triiodothyronine, simulated metabolic acidosis and inhibition of the chromogenic lysate assay for endotoxin. Heparin may interfere with the determination of aminoglycosides by immunoassays.

4.6 Special Populations

Pregnancy

Risk Summary

There are no available data on heparin sodium use in pregnant women to inform a drug associated risk of major birth defects and miscarriage. In published reports, heparin exposure during pregnancy did not show evidence of an increased risk of adverse maternal or fetal outcomes in humans. No teratogenicity, but early embryo-fetal death was observed in animal reproductive studies with administration of heparin sodium to pregnant rats and rabbits during organogenesis at doses approximately 10 times the maximum recommended human dose (MRHD) of 45,000 units/24hours infusion Consider the benefits and risks of heparin sodium injection to a pregnant woman and possible risks to the fetus when prescribing heparin sodium injection to a pregnant woman.

There are no known adverse outcomes associated with fetal exposure to the preservative benzyl alcohol through maternal drug administration; however, the preservative benzyl alcohol can cause serious adverse events and death when administered intravenously to neonates and infants.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively.

The maternal and fetal outcomes associated with uses of heparin via various dosing methods and administration routes during pregnancy have been investigated in numerous studies. These studies generally reported normal deliveries with no maternal or fetal bleeding and no other complications.

Lactation

Risk Summary

There is no information regarding the presence of heparin in human milk, the effects on the breastfed child, or the effects on milk production. Due to its large molecular weight, heparin is not likely to be excreted in human milk, and any heparin in milk would not be orally absorbed by a breastfed child. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for heparin sodium injection and any potential adverse effects on the breastfed child from heparin sodium injection or from the underlying maternal condition. Benzyl alcohol present in maternal serum is likely to cross into human milk and may be orally absorbed by a nursing infant.

Pediatric Use

There are no adequate and well controlled studies on heparin use in pediatric patients. Pediatric dosing recommendations are based on clinical experience.

Carefully examine all heparin sodium injection vials to confirm choice of the correct strength prior to administration of the drug. Pediatric patients, including neonates, have died as a result of medication errors.

Benzyl Alcohol Toxicity

Serious adverse reactions including fatal reactions and the "gasping syndrome" occurred in premature neonates and low-birth weight infants in the neonatal intensive care unit who received benzyl alcohol as a preservative in infusion solutions.

In these cases, benzyl alcohol dosages of 99 to 234 mg/kg/day produced high levels of benzyl alcohol and its metabolites in the blood and urine (blood levels of benzyl alcohol were 0.61 to 1.378 mmol/L). Additional adverse reactions included gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse. Preterm, low-birth weight infants may be more likely to develop these reactions because they may be less able to metabolize benzyl alcohol.

When prescribing heparin sodium injection in infants consider the combined daily metabolic load of benzyl alcohol from all sources including heparin sodium injection and other drugs containing benzyl alcohol. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known.

Geriatric Use

There are limited adequate and well-controlled studies in patients 65 years and older, however a higher incidence of bleeding has been reported in patients over 60 years of age, especially women. Lower doses of heparin may be indicated in these patients

4.7 Effects on ability to drive and use machines

There is no established data available.

4.8 Undesirable Effects

Hemorrhage

Hemorrhage is the chief complication that may result from heparin therapy. An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug.It should be appreciated that gastrointestinal or urinary tract bleeding during anticoagulant therapy may indicate the presence of an underlying occult lesion. Bleeding can occur at any site but certain specific hemorrhagic complications may be difficult to detect:

•Adrenal hemorrhage, with resultant acute adrenal insufficiency, has occurred during anticoagulant therapy. Therefore, such treatment should be discontinued in patients who develop signs and symptoms of acute adrenal hemorrhage and insufficiency. Initiation of corrective therapy should not depend on laboratory confirmation of the diagnosis, since any delay in an acute situation may result in the patient's death.

•Ovarian (corpus luteum) hemorrhage developed in a number of women of reproductive age receiving short- or long-term anticoagulant therapy. This complication if unrecognized may be fatal.

•Retroperitoneal hemorrhage.

Local irritation

Local irritation, erythema, mild pain, hematoma or ulceration may follow deep subcutaneous (intrafat) injection of heparin sodium. These complications are much more common after intramuscular use, and such use is not recommended.

Hypersensitivity

Generalized hypersensitivity reactions have been reported, with chills, fever, and urticaria as the most usual manifestations, and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid reactions, including shock, occurring more rarely. Itching and burning, especially on the plantar site of the feet, may occur.

Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0–30%. While often mild and of no obvious clinical significance, a reduction in platelet count can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death.

Certain episodes of painful, ischemic, and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia associated complications remains to be determined.

Miscellaneous

Osteoporosis following long-term administration of high-doses of heparin, cutaneous necrosis after systemic administration, suppression of aldosterone synthesis, delayed transient alopecia, priapism, and rebound hyperlipemia on discontinuation of heparin sodium have also been reported.

Significant elevations of aminotransferase (SGOT [S-AST] and SGPT [S-ALT]) levels have occurred in a high percentage of patients (and healthy subjects) who have received heparin.

4.9 Overdosage

Bleeding is the chief sign of heparin overdosage.

Neutralization of Heparin Effect

When clinical circumstances (bleeding) require reversal of the heparin effect, protamine sulfate (1% solution) by slow infusion will neutralize heparin sodium. No more than 50 mg should be administered, very slowly, in any 10 minute period. Each mg of protamine sulfate neutralizes approximately 100 IP heparin units. The amount of protamine required decreases over time as heparin is metabolized. Although the metabolism of heparin is complex, it may, for the purpose of choosing a protamine dose, be assumed to have a half-life of about 30 minutes after intravenous injection. Because fatal reactions often resembling anaphylaxis have been reported with protamine, it should be given only when resuscitation techniques and treatment of anaphylactoid shock are readily available.

5. Pharmacological Properties

5.1 Mechanism of Action

Heparin interacts with the naturally occurring plasma protein, Antithrombin III, to induce a conformational change, which markedly enhances the serine protease activity of Antithrombin III, thereby inhibiting the activated coagulation factors involved in the clotting sequence, particularly Xa and IIa. Small amounts of heparin inhibit Factor Xa, and larger amounts inhibit thrombin (Factor Ia). Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor. Heparin does not have fibrinolytic activity; therefore, it will not lyse existing clots.

5.2 Pharmacodynamic Properties

Serious adverse reactions including fatal reactions and the "gasping syndrome" occurred in premature neonates and low-birth weight infants in the neonatal intensive care unit who received benzyl alcohol as a preservative in infusion solutions.

5.3 Pharmacokinetic Properties

Absorption

Heparin is not absorbed through the gastrointestinal tract and therefore administered via parenteral route. Peak plasma concentration and the onset of action are achieved immediately after intravenous administration.

Distribution

Heparin is highly bound to antithrombin, fibrinogens, globulins, serum proteases and lipoproteins. The volume of distribution is 0.07 L/kg.

Elimination

Metabolism

Heparin does not undergo enzymatic degradation.

Excretion

Heparin is mainly cleared from the circulation by liver and reticuloendothelial cells mediated uptake into extravascular space. Heparin undergoes biphasic clearance, a) rapid saturable clearance (zero order process due to binding to proteins, endothelial cells and macrophage) and b) slower first order elimination. The plasma half-life is dose-dependent and it ranges from 0.5 to 2 h.

Specific Populations

Geriatric patients

Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated partial thromboplastin times (aPTTs) compared with patients under 60 years of age.

6. Non-clinical Properties

6.1 Animal Toxicology or Pharmacology

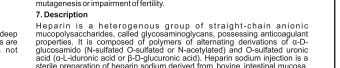
In a published study conducted in rats and rabbits, pregnant animals received heparin intravenously during organogenesis at a dose of 10,000 units/kg/day, approximately 10 times the maximum human daily dose based on body weight. The number of early resorptions increased in both species. There was no evidence of teratogenic effects.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies in animals have been performed to evaluate carcinogenic potential of heparin. No studies in animals have been performed addressing mutagenesis or impairment of fertility.

7. Description

Heparin is a heterogenous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, possessing anticoagulant properties. It is composed of polymers of alternating derivations of α-D-glucosamido (N-sulfated O-sulfated or N-acetylated) and O-sulfated uronic acid (α-L-iduronic acid or β-D-glucuronic acid). Heparin sodium injection is a sterile preparation of heparin sodium derived from bovine intestinal mucosa, standardized for anticoagulant activity, in water for injection. It is intended for intravenous or deep subcutaneous administration.



Structure of heparin sodium

8. Pharmaceutical Particulars

8.1 Incompatibilities

The medicinal product must not be mixed with other medicinal products.

8.2 Shelf-Life – Please see manufacturing date and expiry date printed on the pack.

8.3 Package Information - Heparin Sodium Injection IP 5000 IU filled in a 5ml glass vial and packed in a monocarton.

8.4 Storage : Store in a cool, dry & dark place. (Below 30°C.)

Keep medicine out of reach of children.

9. Patient Counselling Information

Hemorrhage

Inform patients that it may take them longer than usual to stop bleeding, that they may bruise and/or bleed more easily when they are treated with heparin, and that they should report any unusual bleeding or bruising to their physician. Hemorrhage can occur at virtually any site in patients receiving heparin. Fatal hemorrhages have occurred.

Prior to Surgery

Advise patients to inform physicians and dentists that they are receiving heparin before any surgery is scheduled.

Heparin-Induced Thrombocytopenia

Inform patients of the risk of heparin-induced thrombocytopenia (HIT). HIT may progress to the development of venous and arterial thromboses, a condition known as heparin-induced thrombocytopenia and thrombosis (HITT). HIT and HITT can occur up to several weeks after the discontinuation of heparin therapy.

Hypersensitivity

Inform patients that generalized hypersensitivity reactions have been reported. Necrosis of the skin has been reported at the site of subcutaneous injection of heparin.

Other Medications

Because of the risk of hemorrhage, advise patients to inform their physicians and dentists of all medications they are taking, including non-prescription medications, and before starting any new medication.

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