Folding Pattern 75 mm

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Hypersensitivity reactions have been reported with chills, fever, and urticaria as the most usual manifestations. Asthma, rhinitis, lacrimation, and anaphylactoid reactions have also been reported.

Acute, reversible thrombocytopenia has been reported following intravenously administered heparin sodium. Osteoporosis following long-term high-dose administration, aldosterone suppression, delayed transient alopecia, priapism, and rebound hyperlipemia following discontinuation of heparin sodium have also been reported.

OVERDOSAGE

Protamine sulphate (1 % solution) by slow infusion will neutralize heparin. Not more than 50 mg should be given in any 10 minutes period.

Each mg of protamine sulphate neutralizes approximately 100 units of heparin

Decreasing amounts of protamine sulphate are required as the time from the last heparin injection increases. Thirty minutes after a dose of heparin approximately 0.5 mg of protamine is sufficient to neutralize each 120 units of administered heparin Blood or plasma transfusions may be necessary, these dilute but do not neutralize heparin.

Nature and contents of the container

Each 5 mL USP Type 1 Clear glass vial contains 25000IU of Heparin Sodium BP.

Store below 30°C and protect from light, keep out of reach of children.

Manufactured by:

GLAND PHARMA LIMITED.
Sy. No. 143-148, 150 & 151,
Near Gandimaisamma Cross Roads,
D.P. Pally, Dundigal Post,
Dundigal - Gandimaisamma Mandal,
Medchal – Malkajgiri District,
Hyderabad - 500043,
Telangana, India

1313XXXXXX-XX

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

HEPARIN INJECTION B.P. 25000 IU/5 mL

DESCRIPTION

Heparin Injection B.P. is derived from mucosa standardized for use as an anticoagulant in water for injection with 0.95% w/v Benzyl Alcohol as a preservative. The potency is determined by biological assay using a reference standard based upon units of heparin activity per miligram.

MECHANISM

Heparin inhibits the clotting of blood and the formation of fibrin clots both in vitro and in vivo. In combination with a co-factor, it inactivates thrombin thus preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor.

Heparin Sodium inhibits reactions which lead to clotting but does not alter the normal components of the blood. Although clotting time is prolonged by therapeutic doses, bleeding time is usually unaffected. Heparin Sodium does not have fibrinolytic activity, therefore it will not lyse existing clots.

INDICATIONS AND DOSE

Treatment of mild to moderate pulmonary embolism | Treatment of unstable angina | Treatment of acute peripheral arterial occlusion

INITIALLY BY INTRAVENOUS INJECTION

• Adult: Loading dose 5000 units, alternatively (by intravenous injection) loading dose 75 units/kg, followed by (by continuous intravenous infusion) 18 units/kg/hour, laboratory monitoring essential.

preferably on a daily basis, and dose adjusted accordingly

Treatment of severe pulmonary embolism

INITIALLY BY INTRAVENOUS INJECTION

• Adult: Loading dose 10 000 units, followed by (by continuous intravenous infusion) 18 units/kg/hour,laboratory monitoring essential.preferably on a daily basis, and dose adjusted accordingly.

Treatment of deep-vein thrombosis

INITIALLY BY INTRAVENOUS INJECTION

• Adult: Loading dose 5000 units, alternatively (by intravenous injection) loading dose 75 units/kg, followed by (by continuous intravenous infusion) 18 units/kg/hour, alternatively (by subcutaneous injection) 15 000 units every 12 hours, laboratory monitoring essential.

preferably on a daily basis, and dose adjusted accordingly

Thromboprophylaxis in medical patients

BY SUBCUTANEOUS INJECTION

• Adult: 5000 units every 8 -12 hours

Thrombophylaxis in surgical patients

BY SUBCUTANEOUS INJECTION

• Adult: 5000 units for 1 dose, to be taken 2 hours before surgery, then 5000 units every 8 -12 hours

Thromboprophylaxis during pregnancy

BY SUBCUTANEOUS INJECTION

• Adult: 5000 -10000 units every 12 hours, to be administered with monitoring, **Important:** prevention of prosthetic heart-valve thrombosis in pregnancy calls for **specialist management**

Haemodialysis

INITIALLY BY INTRAVENOUS INJECTION

150 mm

150 mm

• Adult: Initially 1000 - 5000 units, followed by (by continuous intravenous infusion) 250 -1000 units/hour

Prevention of clotting in extracorporeal circuits

TO THE DEVICE AS A FLUSH

• Adult: (consult product literature)

To maintain patency of catheters, cannulas, other indwelling intravenous infusion devices

TO THE DEVICE AS A FLUSH

• Adult: 10-200 units, to be flushed through every 4-8 hours, not for therapeutic use

SURGERY OF THE HEART AND BLOOD VESSELS:

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 of heparin sodium per kilogram of body weight is used for procedures estimated to last less than 60 minutes.

BLOOD TRANSFUSIONS

Addition of 400 to 600 units per 100 ml of whole blood. Usually 7,500 Heparin Sodium Units is added to 100 ml of Sterile Sodium Chloride injection and mixed (or 75,000 units per 1,000 ml of sodium chloride injection) and from this sterile solution, 6 ml to 8 ml is added per 100 ml of whole blood. Leukocyte counts should be performed on Heparinized blood within two hours after addition of the heparin. Heparinized blood should not be used for isoagglutin, compliment or erythrocyte fragility tests.

LABORATORY SAMPLES

Addition of 70 to 150 units of heparin sodium per 10 to 20 ml sample of whole blood are usually employed to prevent coagulation of the sample

CONTRAINDICATIONS

Hypersensitivity to Heparin.

Inability to perform suitable blood coagulation tests, e.g. the whole blood clotting time, partial thromboplastin time, etc., at required intervals. Uncontrollable bleeding.

- Acute bacterial endocarditis.
- after major trauma .
- Epidural anaesthesia with treatment doses.
- haemophilia and other haemorrhagic disorders.
- peptic ulcer.recent cerebral haemorrhage.
- recent surgery to eye. recent surgery to nervous system.
- severe hypertension. spinal anaesthesia with treatment doses .
- thrombocytopenia (including history of heparin-induced thrombocytopenia)
- **CAUTIONS**: Elderly

WARNINGS: Heparin Sodium should be used with extreme caution in disease states where there is increased danger of haemorrhage.

Not to be used in newly born or premature infants

Heparin injection B.P. when used in therapeutic dosage should be regulated by frequent blood coagulation tests. If the coagulation test is unduly prolonged or if haemorrhage occurs, Heparin Sodium should be promptly discontinued.

Some of the conditions in which increased danger of haemorrhage exists are as follows:

Cardiovascular	subacute bacterial endocarditis; arterial sclerosis; increased capillary permeability, during and immediately following major surgery,.especially of brain, spinal cord and eye.
Haematologic	Conditions associated with increased bleeding tendencies such as haemophilia, some purpuras and thrombocytopenia.
Gastro-intestinal	Inaccessible ulcerative lesions; continuous tube drainage of stomach or small intestine.

Heparin Sodium may prolong the one-stage prothrombin time Accordingly, when heparin sodium is given with bishydroxycoumarin or sodium warfarin, a period of 4 to 5 hours after the last intravenous dose and 12 to 24 hours after the last subcutaneous (intrafat) dose of heparin sodium should elapse before blood is drawn, if a valid prothrombin time is to be obtained.

Salicylates may induce bleeding and should be used with caution in patients on heparin. Any drug which may induce prolongation of the prothrombin time or delay coagulation by any means, e.g. interference with platelet aggregation, etc., should likewise be used with caution.

While there is experimental evidence that heparin may antagonize the action of ACTH, insulin, or corticosteroids. This effect has not been clearly defined

There is likewise evidence in experimental animals that heparin may modify or inhibit allergic reactions. However, the application of these findings to human patients, has not been fully defined. Larger doses of heparin maybe necessary in the febrile state. The use of digitalis, tetracyclines, nicotine and antihistamines may partially counteract the anticoagulant action of heparin. An increased resistance to heparin is frequently encountered in case of thrombosis, thromboflebitis infections with thrombosing tendency, myocardial infarction, cancer, and in the postoperative patients.

This product contains Benzyl alcohol as preservative. Benzyl alcohol has been reported to be associated with a fatal "Gasping syndrome" in premature infants. Hence the product should not be used in newly born or premature infants.

PRECAUTIONS

1) Allergic Conditions

Because Heparin injection is derived from animal tissue, it should be used with caution in patients with a history of allergy. Before a therapeutic dose is given to such a patient a trial dose of 1000 units may be advisable.

2) Pregnancy

Heparin injection should be used with caution during pregnancy, especially during the last trimester (even though heparin does not cross the placental barrier) and in the immediate post partum period. It should also be used with caution in the presence of mild hepatic or renal disease, hypertension, during menstrutation, or in patients with in-dwelling catheters. A higher incidence of bleeding may be seen in women over 60 years of age.

ADVERSE REACTIONS

Haemorrhage is the chief complication which may develop as a result of heparin therapy. An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug.

When administered intramuscularly, heparin sodium may produce local irritation, mild pain, or haematoma at the injection site. These effects are less frequently seen following deep subcutaneous (intrafat) administration. Histamine - like reactions have also been observed at the site of injection.