



## HEPARIN INJECTION BP

### Presentation

Heparin Injection BP 1,000 units per ml: each ml contains 1,000 units Heparin Sodium (mucous) with 1% Benzyl Alcohol as preservative. Other ingredients: Sodium Chloride, Water for injections.

Heparin Injection BP 5,000 units per ml: each ml contains 5,000 units Heparin Sodium (mucous) with 1% Benzyl Alcohol as preservative. Other ingredients: Sodium Chloride, Water for injections.

Heparin Injection BP 25,000 units per ml: each ml contains 25,000 units Heparin Sodium (mucous) with 1% Benzyl Alcohol as preservative. Other ingredients: Water for injections.

### Uses

**Mode of Action:** Heparin is a naturally occurring anti-coagulant which prevents the coagulation of blood in-vivo and in-vitro. It potentiates the inhibition of several activated coagulation factors, including thrombin and factor X.

**Indications:** Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis, pulmonary embolism, fat embolism.

Prophylaxis against deep vein thrombosis and thromboembolic events in susceptible patients.

### Dosage and administration

#### Treatment dosage

**Intravenous administration:** 5,000 - 10,000 units every 4 hours or 500 units/kg body-weight daily as a continuous infusion in sodium chloride injection or dextrose injection. The dose should be individually adjusted according to coagulation tests.

**Subcutaneous administration:** The initial dose is 250 units/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time, whole blood clotting time or activated partial thromboplastin time 1.5 - 2 times that of control on blood withdrawn 4 - 6 hours after the first injection or commencement of infusion and at similar intervals until the patient is stabilised.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 units should be given 2 hours preoperatively 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 units should be given twice daily for 10 days or until the patient is mobile.

**Other patients:** 5,000 units should be given every 8 - 12 hours.

#### Dosage in children

**Treatment dosage:** Standard treatment dosages should be given initially. Subsequent dosages and/or dosage intervals should be individually adjusted according to changes in thrombin clotting time, whole blood clotting time and/or activated partial thromboplastin time.



### Dosage in the elderly

**Treatment dosage:** Lower treatment dosages may be required, however, standard treatment dosages should be given initially and then subsequent dosages and/or dosage intervals should be individually adjusted according to changes in thrombin clotting time, whole blood clotting time and/or activated partial thromboplastin time.

**Prophylactic dosage:** Dosage alterations are unnecessary for prophylaxis in the elderly.

### Pregnancy

**Treatment dosage:** Standard treatment dosages should be given initially by continuous intravenous infusion or every 12 hours by subcutaneous injection. Intermittent intravenous injections are not advised. Subsequent dosages and/or dosage intervals should be individually adjusted according to changes in thrombin clotting time, whole blood clotting time and/or activated partial thromboplastin time.

**Prophylactic dosage:** It is recommended that plasma heparin levels be maintained below 0.4 units/ml, as determined by specific anti-Xa assay. A suggested dosage is 5,000 units every 12 hours in the early pregnancy, increasing to 10,000 units every 12 hours in the last trimester. The dosage should be reduced during labour and the standard prophylactic dosage is suitable in the puerperium.

### Contra-indications, warnings, etc.

**Contra-indications:** Haemorrhagic disorders and patients with an actual or potential bleeding site e.g. peptic ulcer.

Heparin Injection BP contains Benzyl Alcohol and is therefore contra-indicated in newborn infants, especially in immature neonates.

**Precautions:** Heparin therapy should be given with caution to patients with impaired renal or hepatic function.

Oral anticoagulants or drugs which interfere with platelet function, eg aspirin and dextran solutions should be administered with caution.

**Pregnancy and lactation:** Although animal studies have not been performed, epidemiological studies indicate that if drug therapy is needed in pregnancy, the use of heparin in the recommended dosage is acceptable. Heparin does not cross the placenta or appear in breast milk.

**Adverse reactions:** Hypersensitivity and acute reversible thrombocytopenia may occur rarely. Osteoporosis and alopecia have been reported after prolonged therapy.

**Overdosage:** The effect of heparin can be reversed immediately by intravenous administration of a 1% protamine sulphate solution. The dose of protamine sulphate required for neutralisation should be determined accurately by titrating the patient's plasma. It is important to avoid overdosage of protamine sulphate because protamine itself has anticoagulant properties. A single dose of protamine sulphate should never exceed 50 mg. Intravenous injection of protamine may cause a sudden fall in blood pressure, bradycardia, dyspnoea and transitory flushing, but these may be avoided or diminished by slow and careful administration.

### Pharmaceutical precautions

Store below 25 °C.

Heparin has been reported to be incompatible in aqueous solutions with certain substances, eg some antibiotics, hydrocortisone and phenothiazines, narcotic analgesics and some antihistamines.

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