

Heparin Sodium Injection USP 1000 Units/1ml, 5000 units/5ml, 25000 units/5ml

1. Name of the medicinal product

Heparin Sodium Injection USP 1000
Units/1ml Taj Pharma

Heparin Sodium Injection USP 5000
Units/5ml Taj Pharma

Heparin Sodium Injection USP 25000
Units/5ml Taj Pharma

2. Qualitative and quantitative composition

a) Heparin Sodium Injection USP 1000
Units/1ml
Each ml contains:

Heparin Sodium	1000 Units
Sodium Chloride	8.6mg
Benzyl alcohol	0.001ml

b) Heparin Sodium Injection USP 5000
Units/5ml
Each ml contains:

Heparin Sodium	1000 Units
Sodium Chloride	8.6mg
Benzyl alcohol	0.001ml

c) Heparin Sodium Injection USP 25000
Units/5ml
Each ml contains:

Heparin Sodium	5000 Units
Sodium Chloride	8.6mg
Benzyl alcohol	0.001ml

3. Pharmaceutical form

Solution for Injection.

4. Clinical particulars

4.1 Therapeutic indications

To maintain the patency of in-dwelling intravenous lines. It is not recommended for therapeutic use.

4.2 Posology and method of administration

Method of administration

For routine use, 2 ml containing 200 IU of heparin should be administered into the catheter/cannula every 4-8 hours or as required.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the other excipients listed in section 6.1 Current or history of heparin induced thrombocytopenia.

Heparin Sodium 100 IU/ml i.v. flush solution contains 10 mg/ml of the preservative benzyl alcohol. This formulation must not be given to premature babies or neonates.

4.4 Special warnings and precautions for use

Heparin Sodium 100 IU/ml i.v. flush solution should be used with caution in patients with hypersensitivity to low molecular weight heparin.

Rigorous aseptic technique should be observed at all times in its use.

As there is a risk of antibody-mediated heparin-induced thrombocytopenia, platelet counts should be measured in patients receiving regular and repeated use of heparin flush solutions for longer than 5 days (or earlier in patients with previous exposure to heparin) treatment should be stopped immediately in those who develop thrombocytopenia or paradoxical thrombosis, heparin should immediately be eliminated from all flushes and ports.

Heparin induced thrombocytopenia and heparin induced thrombocytopenia with thrombosis can occur up to several weeks after discontinuation of heparin therapy. Patients presenting with thrombocytopenia or thrombosis after discontinuation of heparin should be evaluated for HIT and HITT.

Repeated flushing of a catheter device with heparin may result in a systemic anticoagulant effect.

Heparin Sodium 100 IU/ml i.v. flush solution contains the preservative benzyl alcohol 10mg/ml. This product should be administered with caution to infants and children up to 3 years old, as there is a risk that benzyl alcohol may cause toxic and allergic reactions (anaphylactoid) in this age group (see also section 4.3 for premature babies or neonates).

Heparin Sodium 100 IU/ml i.v. flush solution contains esters of parahydroxybenzoates as a preservative system. These may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

For incompatibilities with other medicinal products see Section 6.2.

When an indwelling device is used for repeated withdrawal of blood samples for laboratory analyses and the presence of heparin or saline is likely to interfere with or alter the results of the tests, the in situ heparin flush solution should be cleared from the device by aspirating and discarding a volume of solution equivalent to that of the indwelling venipuncture device before the desired blood sample is taken.

4.6 Fertility, pregnancy and lactation

The safety of Heparin Sodium 100 I.U./ml Flushing Solution in pregnancy is not established but the dose of heparin used would not be expected to constitute a hazard. However, as benzyl alcohol may cross the placenta, the use of Heparin Sodium 100 IU/ml i.v. flush solution containing benzyl alcohol should be avoided during pregnancy.

Heparin does not cross the placental barrier and is not excreted in breast milk.

4.7 Effects on ability to drive and use machines

Heparin has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

When used as recommended, the low dose of heparin reaching the blood is extremely unlikely to have any systemic effects. However, there have been rare reports of immune-mediated thrombocytopenia and thrombosis in patients receiving heparin flushes (see also Section 4.4, Special Warnings and Precautions for Use)..

Hypersensitivity reactions to heparin are rare. They include urticaria, conjunctivitis, rhinitis, asthma, cyanosis, tachypnoea, feeling of oppression, fever, chills, angioneurotic oedema and anaphylactic shock.

Local irritation may occur if inadvertently injected subcutaneously.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet.

4.9 Overdose

An overdose is unlikely to occur. Bleeding is the main sign of overdose with heparin. As heparin is eliminated quickly, a



discontinuation of treatment is sufficient in case of minor haemorrhages. In case of severe haemorrhages heparin may be neutralised with protamine sulphate injected slowly intravenously. One mg of protamine sulphate neutralises approximately 100 IU of heparin. Nevertheless, the required protamine sulphate dose varies according to the time of heparin administration and the dose administered.

It is important to avoid overdosage of protamine sulphate because protamine sulphate itself has anticoagulant properties. A single dose of protamine sulphate should never exceed 50 mg. Intravenous injection of protamine sulphate 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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Heparin is a naturally occurring anticoagulant 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.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl alcohol,

Methylparahydroxybenzoate,

Propylparahydroxybenzoate,

Sodium citrate,

Sodium chloride,

Water for Injections.

6.2 Incompatibilities

This product is compatible with normal saline. Heparin has been reported to be incompatible in aqueous solution with certain substances, e.g. some antibiotics, hydrocortisone, phenothiazines, narcotic analgesics and antihistamines.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

10 x 2 ml ampoules.

6.6 Special precautions for disposal and other handling

None

7. Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214. Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at: Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com