SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Heparin sodium 100 lU/ml IV Flush Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Heparin sodium Ph. Eur. 100 IU/ml

Excipient(s) with known effect:
- one ml of solution contains 1.05 mg methyl parahydroxybenzoate
- one ml of solution contains 0.21 mg propyl parahydroxybenzoate
- one ml of solution contains 10 mg benzyl alcohol 10mg/ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To maintain the patency of in-dwelling intravenous lines.
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.

Use in premature infants or neonates.

Concomitant use of intravenous diclofenac.

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). Heparin treatment should be stopped immediately in those who develop thrombocytopenia or paradoxical thrombosis and heparin should immediately be eliminated from all flushes and ports.

Heparin induced thrombocytopenia (HIT) and heparin induced thrombocytopenia with thrombosis (HITT) 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 or HITT.

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

This medicine contains less than 1 mmol sodium (23 mg) per 100 International Units (IU) dose, that is to say essentially ‘sodium-free’.

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).

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

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

Pregnancy

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.

Breast-feeding

Heparin 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

Used as directed, it is extremely unlikely that the low levels of heparin reaching the blood will have any systemic effects, however, there have been rare reports of immune-mediated thrombocytopenia and thrombosis in patients receiving heparin flushes (see section 4.4). Pulmonary embolism has been reported as thromboembolic complications of heparin-induced thrombocytopenia.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Heparin is a naturally occurring anticoagulant which prevents the coagulation of blood *in-vivo* and *in-vitro*. The dose used to flush indwelling devices is unlikely to produce blood levels of heparin having any systemic effect.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol

Methyl parahydroxybenzoate

Propyl parahydroxybenzoate

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.

Heparin and reteplase are incompatible when combined in solution.

Amikacin sulfate, gentamicin sulfate, netilmicin sulfate, pethidine hydrochloride, promethazine hydrochloride and tobramycin sulfate.

If reteplase and heparin are to be given through the same line this, together with any Y-lines, must be thoroughly flushed with a 0.9% saline or a 5% glucose solution prior to and following the reteplase injection.

6.3 Shelf life

3 years.

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Do not store above 25^0 C.

6.5 Nature and contents of container

10 x 2 ml ampoules.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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