Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Heparin Sodium 10 I.U./ml flushing solution for maintenance of patency of intravenous devices

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Heparin sodium 10 I.U./ml (50 I.U. in 5 ml)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Flushing solution for the maintenance of patency of intravenous devices.
A colourless or straw coloured liquid, free from turbidity and from matter that deposits on standing.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Heparin is an anticoagulant and acts by potentiating the naturally occurring inhibitors of thrombin and factor X (Xa).

Heparin Sodium 10 I.U./ml Flushing Solution is indicated in any clinical circumstances inwhich it is desired to maintain the patency of indwelling catheters/cannulae, attendant lines or heparin locks.

4.2 Posology and method of administration

Heparin Sodium 10 I.U./ml Flushing Solution is not recommended for systemic use.

For cleaning indwelling cannulae.

Material to be used as a cannula flush (5ml; 50 units) every four hours or as required.

4.3 Contraindications

The very rare occurrence of established hypersensitivity to heparin is the only contraindication to Heparin Sodium 10 I.U./ml Flushing Solution.
Concomitant use of intravenous diclofenac with heparin (including low dose heparin) is contraindicated.

4.4 Special warnings and precautions for use

Caution should be exercised in patients with known hypersensitivity to lowmolecular weight heparins.

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. In patients who develop thrombocytopenia or paradoxical thrombosis, heparin treatment should be stopped immediately and heparin 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.

4.5 Interaction with other medicinal products and other forms of interactions

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 results of the desired blood 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 10 I.U./ml Flushing Solution in pregnancy is not established, but the dose of heparin involved would not be expected to constitute a hazard.

Heparin does not appear in breast milk.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Used as directed, it is extremely unlikely that the low levels of heparin reaching the blood will have any systemic effect, however, there have been rare reports of immune-mediated thrombocytopenia and thrombosis in patients receiving heparin flushes.
Pulmonary embolism has been reported as thromboembolic complications of heparin-induced thrombocytopenia. Heparin should be discontinued immediately in patients who develop 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Heparin Sodium 10 I.U./ml Flushing Solution containing only 50 iu of sodium heparin per ampoule (5ml), is used for flushing indwelling cannulae. This is unlikely to produce blood levels of heparin having any systemic effect.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections
Hydrochloric acid
Sodium hydroxide

6.2 Incompatibilities

The following drugs are incompatible with heparin;

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

Heparin and reteplase are incompatible when combined in solution.
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

Unopened 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°C.
Store in the original package.

6.5 Nature and contents of container

Neutral glass ampoules (Type I Ph Eur) of 5ml capacity containing 5ml of solution. Carton contains 10 ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd,
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0281/230/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 November 1985

Date of last renewal: 14 November 2005

10 DATE OF REVISION OF THE TEXT

December 2020