

Package leaflet: Information for the user
HEPARIN SODIUM 10 I.U./ML FLUSHING SOLUTION FOR MAINTENANCE OF
PATENCY OF INTRAVENOUS DEVICES

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Heparin Sodium 10 I.U./ml Flushing Solution for maintenance of patency of intravenous devices. In the rest of this leaflet, it is called Heparin Sodium 10 I.U./ml Flushing Solution.

What is in this leaflet

1. What Heparin Sodium 10 I.U./ml Flushing Solution is and what it is used for
2. What you need to know before you use Heparin Sodium 10 I.U./ml Flushing Solution
3. How to use Heparin Sodium 10 I.U./ml Flushing Solution
4. Possible side effects
5. How to store Heparin Sodium 10 I.U./ml Flushing Solution
6. Contents of the pack and other information

1. What Heparin Sodium 10 I.U./ml Flushing Solution is and what it is used for

Heparin Sodium 10 I.U./ml Flushing Solution is heparinised saline which is heparin dissolved in a salt water solution.

Heparin is an anti-clotting agent and is produced naturally in the body. Heparin Sodium 10 I.U./ml Flushing Solution is used to wash and rinse the inside of catheters, cannulas and other surgical forms of tubing to ensure they do not become blocked while they are in use.

2. What you need to know before you use Heparin Sodium 10 I.U./ml Flushing Solution

Do not use Heparin Sodium 10 I.U./ml Flushing Solution if:

- you have been told you are allergic to heparin.
- you are about to be treated for pain and inflammation with intravenous diclofenac

Take special care with Heparin flush

Before you have Heparin flush, tell your doctor:

-If you are allergic (hypersensitive) to low molecular weight heparins, such as tinzaparin, enoxaparin or dalteparin.

If you have Heparin flush regularly for more than five days, your doctor may take regular blood tests. This is to check the level of platelets (a type of cell) in your blood while you have your medicine. Depending on the result the doctor may tell you to stop having this medicine straight away.

Also your doctor may take a blood test up to several weeks after the end of your heparin treatment. Again, this is so the doctor can check the level of the platelets in your blood.

Pregnancy, breast-feeding and fertility

Do not use Heparin Sodium 10 I.U./ml Flushing Solution if you are pregnant or trying to become pregnant without talking to your doctor first.

Do not use Heparin Sodium 10 I.U./ml Flushing Solution if you are breast-feeding without talking to your doctor.

If you have any doubts about whether Heparin Sodium 10 I.U./ml Flushing Solution should be used for you then discuss things more fully with your doctor or nurse.

3. How to use Heparin Sodium 10 I.U./ml Flushing Solution

- Heparin Sodium 10 I.U./ Flushing Solution should not be injected directly into the body.
- Heparin Sodium 10 I.U./ml Flushing Solution is used for cleaning catheters, cannulas and other surgical forms of tubing by flushing with 5ml (50 units) every four hours or as required.
- The doctor will decide which dose is best to be used.
- If blood for tests are to be taken from the tubing which has been rinsed with this product, the heparin in the tubing should first be withdrawn and discarded.
- Aseptic techniques should be used at all times during its use to avoid contamination.
- Your doctor will check your blood if you use Heparin Sodium 10 I.U./ml Flushing Solution for longer than five days.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them, particularly when treatment is first started.

- It can cause bleeding and occasionally a serious blood disorder (thrombocytopenia).
- Thrombocytopenia may result in the formation of dangerous blood clots causing chest pains, shortness of breath, coughing, feeling faint, dizziness or loss of consciousness. If thrombocytopenia develops, Heparin treatment should be stopped immediately.

- Rarely, allergic reactions can occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below.

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. How to store Heparin Sodium 10 I.U./ml Flushing Solution

Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the ampoule. The expiry date refers to the last day of that month.
- Do not use if the contents of the ampoule show signs of deterioration such as discolouration.
- Do not store above 25°C.
- Store in the original package in order to protect from light.
- Any portion of the contents not used at once should be discarded.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Heparin Sodium 10 I.U./ml Flushing Solution contains

Heparin Sodium 10 I.U./ml Flushing Solution is heparinised saline which is heparin dissolved in a salt water solution. It is available as a sterile heparinised saline flush solution in one strength of 10 international units per ml. Each 5ml ampoule contains 50 international units of heparin sodium.

The active substance is heparin sodium. The other ingredients are sodium chloride, water for injections, hydrochloric acid and sodium hydroxide.

What Heparin Sodium 10 I.U./ml Flushing Solution looks like and contents of the pack

Heparin Sodium 10 I.U./ml Flushing Solution is a colourless or straw-coloured liquid. The registered pack size is 10 glass ampoules.

Marketing Authorisation holder and Manufacturer

Marketing Authorisation Holder: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This leaflet was last revised in 12/2020

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 5ml)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Flushing solution for maintenance of patency of intravenous devices

A colourless or straw coloured liquid, free from turbidity, and from matter that deposits on standing.

4. CLINICAL INDICATIONS

4.1 Therapeutic indications

Heparin Sodium 10 I.U./ml Flushing Solution 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 in which 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 low molecular 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 the national reporting system:

Ireland

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 symptoms

None stated

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Heparin Sodium 10 I.U./ml Flushing Solution, containing only 50 I.U. 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 3M

Sodium hydroxide 3M

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

5ml clear glass ampoules. Carton contains 10 ampoules.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd.,
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PA 0281/230/001

MA 154/01601

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

16 November 2007

10 DATE OF REVISION OF THE TEXT

December 2020