Introduction

1. What Heparin Sodium 100 I.U./ml Flushing Solution is and what it is used for

Heparin Sodium 100 I.U./ml Flushing Solution is a dilution of heparin sodium. Heparin is a natural substance that is widely used in medicine as an anticoagulant (a blood thinner). Heparin Sodium 100 I.U./ml Flushing Solution is used to wash and rinse the inside of intravenous catheters and cannulas (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 100 I.U./ml Flushing Solution

Do not use Heparin Sodium 100 I.U./ml Flushing Solution:
- If you are allergic to heparin or any of the other ingredients of this medicine.
- If you have any doubts about whether Heparin Sodium 100 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 100 I.U./ml Flushing Solution

Heparin Sodium 100 I.U./ml Flushing Solution is suitable for use with a low concentration of heparin to ensure patency of a retained catheter or cannula.

4. Possible side effects

Heparin Sodium 100 I.U./ml Flushing Solution is contraindicated in some patients. If you experience any symptoms of side effects, consult your doctor immediately.

5. How to store Heparin Sodium 100 I.U./ml Flushing Solution

Do not use Heparin Sodium 100 I.U./ml Flushing Solution:
- If you have any doubts about whether Heparin Sodium 100 I.U./ml Flushing Solution should be used for you then discuss things more fully with your doctor or nurse.

6. Contents of the pack and other information

As the product is contraindicated in some patients, it is important to consult your doctor if you experience any symptoms of side effects. If you experience any symptoms of side effects, consult your doctor immediately.

7. What is in this leaflet

This leaflet contains important information for you.

8. Additional information

This information is also available from your doctor or pharmacist.

9. Copyright information

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10. Revisions

This document was last updated on [date].

11. Contact information

For further information, please contact:

Customer
Mail: [address]
Tel: [phone number]
Fax: [fax number]

Pharmacology
Mail: [address]
Tel: [phone number]
Fax: [fax number]

12. Disclaimer

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Of serum mediated thrombocytopenia and heparin induced thrombocytopenia in patients receiving heparin flushes. Pulmonary embolism has also been reported as a complication of heparin induced thrombocytopenia. Implications for the prescriber of heparin induced thrombocytopenia, should be discouraged immediately in patients who develop thrombocytopenia.

Heparin currently remains to heparin use. This includes urticaria, conjunctivitis, rhinitis, asthma, oedema, angio-oedema, nausea, vomiting, diarrhoea, blood in stools, urinary dysfunction, angina, myocardial infarction and anaphylactic shock.

Reporting of suspected adverse reactions Reporting suspected adverse reactions after the marketing authorisation of the medicinal product is important. It allows continuous 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 or to report adverse reactions to the MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Heparin Sodium 100 I.U./ml Flushing Solution, containing only 200 I.U./ml of sodium heparin ampoules (2018), is used for flushing indwelling cannulae. This is unlikely to produce blood levels of heparin having any systemic effect.

5.2 Pharmacokinetic properties

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 injection Hydrochloric acid 3M Sodium sulphate 3M

6.2 Incompatibilities Impacts and incompatibilities in patients receiving heparin flushes. Pulmonary embolism has also been reported as a complication of heparin induced thrombocytopenia. Implications for the prescriber of heparin induced thrombocytopenia, should be discouraged immediately in patients who develop thrombocytopenia.

5.4 Special precautions for storage Do not store above 25°C Store in the original package.

5.5 Nature and contents of container Ampoule glass ampoules

5.6 Special precautions for disposal Not applicable.

7 MARKETING AUTHORISATION HOLDER

Wockhardt UK Ltd Ash Road North, Wrexham, LL13 9UF, UK

8 MARKETING AUTHORISATION NUMBER(S)

UK.

Date of first authorisation: 11 September 2007

9 DATE OF REVISION OF THE TEXT

June 2018

3. How to use Heparin Sodium 100 I.U./ml Flushing Solution

- Heparin Sodium 100 I.U./ml Flushing Solution should not be injected directly into the body.
- Heparin Sodium 100 I.U./ml Flushing Solution is used for cleaning catheters and cannulae (tubing forms of flushing with heparin).
- The doctor will decide which dose is best to be used.
- If blood from the heparin tubing has been mixed 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 100 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, breathlessness, 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 Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Heparin Sodium 100 I.U./ml Flushing Solution

Keep the 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 refill if the ampoules 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 one time 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 100 I.U./ml Flushing Solution contains

Heparin Sodium 100 I.U./ml Flushing Solution is heparinised saline which is heparin dissolved in a saline water solution. It is available as a sterile heparinised saline flush solution in one strength of 100 international units per ml. Each 2ml ampoule contains 200 international units of heparin sodium. The active substance is heparin sodium.

What Heparin Sodium 100 I.U./ml Flushing Solution looks like and contents of the pack

Heparin Sodium 100 I.U./ml Flushing Solution is a colourless or straw-coloured liquid.
The registered pack size is 10 glass ampoules.

Other formats:
- To listen to or request a copy of this leaflet in Braille, large print or audio please call: free of charge: 0800 138 5000 (UK Only).
- Please be ready to give the following information:

Product Name Reference Number
Heparin Sodium 100 I.U./ml Flushing Solution 29681/0111

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation holder and Manufacturer
Marketing Authorisation holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK
Manufacturer: CPI Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This leaflet was last revised in 06/2018

6.3 Shelf life

From a microbiological point of view, unless the product is kept cold, the product should be used immediately. If not used immediately, in-use storage conditions and times are the responsibility of the user.

6.4 Special precautions for storage

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6.5 Nature and contents of container

Ampoule glass ampoules

6.6 Special precautions for disposal

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