

PACKAGE LEAFLET: INFORMATION FOR THE USER
Heparin sodium 100 IU/ml I.V. flush solution

Read all of this leaflet carefully before you start taking 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 ask your doctor, pharmacist or nurse.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Heparin flush is and what it is used for
2. What you need to know before you are given Heparin flush
3. How Heparin flush is given
4. Possible side effects
5. How to store Heparin flush
6. Contents of the pack and other information

1. WHAT HEPARIN FLUSH IS AND WHAT IT IS USED FOR

Heparin flush belongs to a group of medicines called anticoagulants. It helps to stop the blood from clotting.

Heparin flush is given into an intravenous (I.V.) line. This means it is injected into the tube connected to a vein to keep it clear by preventing the blood from clotting in it. It is not recommended for treatment of harmful blood clots in your body.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN HEPARIN FLUSH

Do not have Heparin flush

- If you are allergic (hypersensitive) to heparin or any of the other ingredients of this medicine. You can find a list of these ingredients in section 6 of this leaflet.
- If you know that you have, or have ever had, a big drop in the clotting cells

(platelets) in your blood thrombocytopenia)

- If you are about to be treated for pain and inflammation with intravenous diclofenac

Do not give this medicine to a premature baby, a newborn baby, or a baby up to a month old.

Take special care with Heparin flush

Before you have Heparin flush, tell your doctor:

- If you are pregnant or think you are pregnant. Read the section "Pregnancy and breast-feeding".
- If you are allergic (hypersensitive) to low molecular weight heparins, such as tinzaparin, enoxaparin or dalteparin.
- If this medicine is for a child who is between one month and three years old.
- If you know that you are sensitive to methylparahydroxybenzoate or propylparahydroxybenzoate. Read the information in the section "Important information about some of the ingredients of Heparin flush".

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.

Taking other medicines

Please tell your doctor or nurse if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Pregnancy and breast-feeding

Unless your doctor has told you it is essential, you must not have Heparin flush if you are pregnant, or think you are pregnant.

Read the information about benzyl alcohol in the section "Important information about some of the ingredients of Heparin flush". If you are pregnant or might be pregnant, tell your doctor before you are given Heparin flush.

If you become pregnant while having this medicine, tell your doctor.

If you are breast-feeding, ask your doctor for advice before having Heparin flush.

Driving and using machines

Usually your medicine may have little effect on your ability to drive or use machines. However, you should check with your doctor if you feel any side effect that may stop you from driving or using machines.

Important information about some of the ingredients of Heparin flush

This medicine contains:

- Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to a new-born baby (up to 4 weeks old).

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

- Methylparahydroxybenzoate and propylparahydroxybenzoate. These are preservatives which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm. This may happen at any time after you have your medicine. Please read section 4 so you can spot any signs this may be happening to you.
- Sodium. This medicine is nearly "sodium free". Your medicine contains less than 23 milligrams (mg) of sodium in each 100 International Units (IU) dose.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. HOW HEPARIN FLUSH IS GIVEN

Heparin flush will be given to you by a doctor or nurse. Heparin flush should not be mixed with any other injection.

The recommended dose of Heparin Flush is

2 ml containing 200 IU of heparin should be administered into the catheter/cannula every 4-8 hours or as required. Your doctor will prescribe the right dose for you.

If you received more Heparin than you should:

You may start to haemorrhage (bleed severely). Please read section 4 so you can spot any signs this may be happening to you. You may be given another injection of a medicine called protamine sulphate.

If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

RJAP108FUF

Customer	Kent Pharma UK Limited
Originated by	DOB (AWG)
Product	Heparin Sodium 100iu/ml I.V. Flush Solution 200 units in 2ml
Dimensions	PIL 250mm x 150mm
Artwork Code	RJAP108FUF
Date	04/11/2020
Proof Number	1

4. POSSIBLE SIDE EFFECTS

When used as recommended the low dose of heparin reaching the blood is unlikely to have any effects on the body. However, information is given here on possible side effects.

Important side effects to look out for include:

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- You have difficulty breathing, wheezing
- Your face or throat swell
- Your skin develops a severe rash
- Hives
- Fever, chills
- Swelling of eyes and lips
- You develop blue tinge to the lips

You should tell your doctor straight away if you spot any of the following signs which mean you may be starting to bleed severely:

- Red or brown urine
- Black tarry stools
- Unusual bruising
- Bleeding from your nose, mouth or any operation wound that will not stop.

Reduction in the number of cells that help your blood clot (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.

You must tell your doctor or nurse immediately. If thrombocytopenia develops, heparin treatment should be stopped immediately.

Thrombocytopenia can occur up to several weeks after the end of your heparin

treatment. As such, your doctor may take a blood test in that time.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE HEPARIN FLUSH

- Keep out of the sight and reach of children.
- Do not use Heparin flush after the expiry date on the label. The expiry date is the last day of that month.
- Store below 25°C.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Heparin flush contains

- The active ingredient is heparin sodium. This product contains 100 IU of heparin sodium in each millilitre (ml).
- The other ingredients are benzyl alcohol, methylparahydroxybenzoate, propylparahydroxybenzoate, sodium chloride, sodium citrate and water for injections.

You can find important information about some of the ingredients near the end of section 2, just before section 3.

What Heparin flush looks like and contents of the pack

Heparin flush is a clear, colourless or pale yellow liquid. This medicine comes in glass ampoules containing 2 ml. There are 10 ampoules in a carton.

Marketing Authorisation Holder:

Kent Pharma UK Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

Manufacturer responsible for batch release:

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Barcelona - Spain

This leaflet was last revised in November 2020.

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