APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

HEPARIN SODIUM 1 000 I.U./1 ml FRESENIUS solution for injection

1 000 I.U. of heparin sodium (mucosal)

HEPARIN SODIUM 5 000 I.U./1 ml FRESENIUS solution for injection

5 000 I.U. of heparin sodium (mucosal)

Sugar free.

Contains preservative: Benzyl alcohol 1,5 % *m/v.*

Read the entire leaflet carefully before you are given HEPARIN SODIUM FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **HEPARIN SODIUM FRESENIUS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

What is in this leaflet

1. What HEPARIN SODIUM FRESENIUS is and what it is used for

HEPARIN SODIUM FRESENIUS belongs to a group of medicines known as anticoagulants. Anticoagulants work by decreasing the clotting ability of your blood and help to stop clots forming in the blood vessels.

HEPARIN SODIUM FRESENIUS injection is used for prevention and treatment of diseases caused by blood clots in your veins and/or arteries.

2. What you need to know before you are given HEPARIN SODIUM FRESENIUS

You should not be given **HEPARIN SODIUM FRESENIUS**:

- if you have an allergy to heparin
- if you have, or may have, a tendency to bleed easily or a problem with your blood vessels
- if you have a low blood platelet count
- in conditions where bleeding is at particular risk, for example:
    - heart problems or high blood pressure
    - blood disease or bleeding problems
    - recent child birth
    - threatened abortion
    - liver disease
    - kidney disease
    - stomach ulcer

- surgery or wounds resulting in large open wounds
- prior to lumber puncture (a procedure performed in order to collect a sample of spinal fluid) or regional anaesthetic block (local anaesthetic block)
- during or after eye, brain, or spinal cord surgery
- pulmonary tuberculosis (TB in the lung).

Warnings and precautions

Special care should be taken with **HEPARIN SODIUM FRESENIUS**.

Tell your doctor or healthcare provider before being given the injection if:

- you are undergoing treatment for lymphoblastic leukaemia (blood cancer),
- you are undergoing renal dialysis**,**
- are over 60 years of age,
- have any condition which makes you likely to bleed more easily. If you are unsure, ask your doctor or nurse,
- have high levels of potassium in your blood or are taking a medicine that may increase the potassium level in your blood,
- suffer from allergies or have previously had an allergic reaction to heparin,
- you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called metabolic acidosis).

Other medicines and HEPARIN SODIUM FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines and **HEPARIN SODIUM FRESENIUS** may interfere with each other. These include:

- Medicines which affect blood clotting such as aspirin and warfarin, epoprostenol, alteplase and dipyridamole.
- Medicines for hay fever such as antihistamines.
- Other nonsteroidal anti-inflammatory medicines (e.g. diclofenac or ibuprofen) for pain.
- Penicillins and other types of antibiotics.
- Medicines which cause increased volume of urine (diuretic).
- Potassium supplements such as potassium-containing salt substitutes.
- Glyceryl trinitrate (for heart disease).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving **HEPARIN SODIUM FRESENIUS**.

HEPARIN SODIUM FRESENIUS does not cross the placenta and therefore adverse effects on the fetus would not be expected. Heparin has not been shown to cause birth defects or bleeding problems in the baby. However, use during the last three months of pregnancy or during the month following the baby's delivery, **HEPARIN SODIUM FRESENIUS** may cause bleeding problems in the mother. Heparin does not pass into the breast milk.

HEPARIN SODIUM FRESENIUS contains the preservative benzyl alcohol. Large amounts of benzyl alcohol can build-up in your body and may cause side effects (called metabolic acidosis).

Driving and using machines

None stated.

HEPARIN SODIUM FRESENIUS contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule and per vial, that is to say essentially sodium free.

HEPARIN SODIUM FRESENIUS contains benzyl alcohol

HEPARIN SODIUM FRESENIUS contains benzyl alcohol (15 mg/ml) as preservative. Benzyl alcohol may cause allergic reactions. The preservative has been linked with the risk of severe side effects including breathing problems (called gasping syndrome) in young children.

3. How you will be given HEPARIN SODIUM FRESENIUS

You will not be expected to administer **HEPARIN SODIUM FRESENIUS** to yourself. Your doctor or healthcare provider will administer **HEPARIN SODIUM FRESENIUS** to you for a specific condition.

HEPARIN SODIUM FRESENIUS injection is usually given directly into your vein (intravenously) or under your skin at regular intervals and at a dose depending on the clotting time of your blood.

HEPARIN SODIUM FRESENIUS can also be given by continuous infusion whereby the **HEPARIN SODIUM FRESENIUS** is mixed with either a dextrose or 0,9 % sodium chloride solution and given by slow injection into your vein (this is called an intravenous infusion).

Your doctor will decide what dose, how often and how long you will receive **HEPARIN SODIUM FRESENIUS**. This depends on your condition and other factors, such as age, blood tests, method it is being given and whether or not other medicines are being given at the same time.

If you receive more HEPARIN SODIUM FRESENIUS than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Symptoms that you need to be aware of in case of an overdose are:

- nose bleeds
- easy or unexplained bruising or bleeding
- blood in your urine or stool.

Tell your doctor if any of the above occurs.

If you missed a dose of HEPARIN SODIUM FRESENIUS

Since a healthcare provider will administer **HEPARIN SODIUM FRESENIUS**, it is unlikely that a dose will be missed.

4. Possible side effects

HEPARIN SODIUM FRESENIUS can have side effects.

Not all side effects reported for **HEPARIN SODIUM FRESENIUS** are included in this leaflet. Should your general health worsen or you experience any untoward effects while receiving **HEPARIN SODIUM FRESENIUS**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop administration of **HEPARIN SODIUM FRESENIUS** immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **HEPARIN SODIUM FRESENIUS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience any of the following reactions after receiving **HEPARIN SODIUM FRESENIUS**:

- any prolonged or unexplained bleeding
- pain, warmth, or redness in your arm or leg which could indicate a blood clot.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you experience any of the following reactions after receiving **HEPARIN SODIUM FRESENIUS**:

Frequency unknown:

- irritation at the site of injection,
- hair loss,
- osteoporosis (following long-term use) – a bone disease that leads to increased bone fractures,
- prolonged, painful erection,

- abnormal results for blood tests that report on how the liver is working,
- high level of blood fats after stopping heparin,
- high or low blood potassium. If affected you may feel tired and weak.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **HEPARIN SODIUM FRESENIUS**.

Health care providers are asked to report any suspected adverse reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the medicine is marketed.

5. How to store HEPARIN SODIUM FRESENIUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

HEPARIN SODIUM FRESENIUS will be stored in the pharmacy or in the hospital wards at or below 25 °C.

After dilution the solutions should be used immediately.

6. Contents of the pack and other information

What HEPARIN SODIUM FRESENIUS contains

The active ingredient in **HEPARIN SODIUM FRESENIUS** is heparin sodium (mucosal).

The other ingredients are benzyl alcohol 1,5 % *m/v* (preservative), sodium chloride, sodium hydroxide (for pH-adjustement), hydrochloric acid (for pH-adjustment) and water for injection.

Each 1 ml clear, colourless glass ampoule or 5 ml clear,colourless glass vial contains heparin sodium (mucosal) dissolved in water for injection, where 1 ml of solution equates to 1 000 IU of heparin sodium (mucosal).

Each 1 ml clear, colourless glass ampoule or 5 ml clear,colourless glass vial contains heparin sodium (mucosal) dissolved in water for injection, where 1 ml of solution contains 5 000 IU of heparin sodium (mucosal).

Benzyl alcohol has been used as a preservative. Heparin is obtained from porcine intestinal mucosa.

What HEPARIN SODIUM FRESENIUS looks like and contents of the pack

HEPARIN SODIUM FRESENIUS solution for injection is a clear, colourless or straw-coloured liquid in clear, colourless glass ampoules or vials, free from turbidity and from matter which deposits on standing.

The 1 ml clear, colourless glass ampoules are packed in 10’s.

The 5 ml clear, colourless glass vials sealed with grey rubber stoppers and aluminium seals are packed in 10’s.

Holder of Certificates of Registration and Manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: 041 403 1600

This leaflet was last revised in

To be allocated by SAHPRA

Registration numbers

HEPARIN SODIUM 1 000 I.U./1 ml FRESENIUS

(1 ml ampoule, 5 ml vial) J/8.2/405

HEPARIN SODIUM 5 000 I.U./1 ml FRESENIUS

(1 ml ampoule, 5 ml vial) J/8.2/406

Access to the corresponding Professional Information

27 March 2023.