PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

FRUSEMIDE 250 mg/25 ml FRESENIUS

solution for injection

Furosemide

Sugar free.

Read all of this leaflet carefully before you are given FRUSEMIDE 250 mg/25 ml FRESENIUS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What FRUSEMIDE 250 mg/25 ml FRESENIUS is and what it is used for

The active ingredient in **FRUSEMIDE 250 mg/25 ml FRESENIUS** is furosemide. Furosemide, as in **FRUSEMIDE 250 mg/25 ml FRESENIUS,** is one of a group of medicines called diuretics. A diuretic helps get rid of excess fluid in the body by causing more urine to be passed.

FRUSEMIDE 250 mg/25 ml FRESENIUS is used to remove excess fluid from the body.

It may also be used when your kidneys are not functioning properly and not producing normal amounts of urine.

2. What you need to know before you are given FRUSEMIDE 250 mg/25 ml FRESENIUS

You should not be given **FRUSEMIDE 250 mg/25 ml FRESENIUS**:

- if you are hypersensitive (allergic) to furosemide, amiloride, sulphonamides, sulphonamide derivatives or any of the other ingredients of **FRUSEMIDE 250 mg/25 ml FRESENIUS** (listed in section 6)
- if you have a low blood volume or are dehydrated (with or without accompanying low blood pressure)
- if you have too little potassium or sodium in your blood (shown in blood test)
- if you have severe liver problems (cirrhosis)
- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**)
- if you are unable to pass urine
- if your kidneys are damaged because of other medicines you took, or if your kidneys stopped working due to liver coma
- if you are not passing any water (urine) or you have been told by a doctor that you have kidney failure
- if you have Addison's disease (a hormonal disorder causing you not to make enough cortisol and other hormones in your adrenal glands)
- if you have too much calcium in your blood
- if you are taking digoxin (used to treat heart problems)
- if you have a condition called porphyria (characterised by stomach pain, vomiting or muscle weakness).

Warnings and precautions

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

- if you have low blood pressure or feel dizzy when you stand up

- if you feel dizzy or dehydrated (if you have lost a lot of water through being sick, having diarrhoea or passing water very often or if you are having trouble drinking or eating)
- if you have low blood levels of essential minerals, like sodium or potassium, or you have acid base imbalance in your body identified by blood tests
- if you are planning to undergo a procedure that includes the use of radiocontrast, do not receive **FRUSEMIDE 250 mg/25 ml FRESENIUS** (as it may increase the risk for kidney damage)
- if you are elderly, are using other medicines which can cause drop in your blood pressure and/or if you have other medical conditions that are risks for decreasing blood pressure
- if you are an elderly patient (your doctor may start you on a lower dose to monitor potential side effects)
- if you have difficulty passing urine (for example caused by a large prostate gland)
- if you have diabetes
- if you have kidney problems
- if you have liver problems
- if you are currently taking antibiotics (e.g. cephalosporins or aminoglycosides) – ringing in the ears and deafness, which may be permanent, may occur in patients with kidney disease or if given with other medicines that have a toxic effect on your hearing (see section 4)
- if you have low blood protein levels (hypoproteinaemia) as this may reduce the effect of **FRUSEMIDE 250 mg/25 ml FRESENIUS** and increase the risk of ear damage
- if you have raised levels of calcium in your blood; careful monitoring of fluids and electrolyte levels are recommended
- if you have a risk of fall in blood pressure
- if you have porphyria (a rare inherited blood disease)
- if you have gout
- if you are on a low sodium diet, as you may lose too much water and get low blood pressure
- if **FRUSEMIDE 250 mg/25 ml FRESENIUS** must be administered to premature infants, as they may be more prone to the development of kidney stones

- if you are an elderly patient or if you have low blood levels of essential minerals like sodium or potassium
- laboratory monitoring – it is recommended to undergo regular monitoring of blood levels for sodium, potassium, kidney function tests (blood urea nitrogen and creatinine levels), glucose, magnesium, calcium, chloride, bicarbonate and uric acid
- regular monitoring is required to check for the occurrence of blood dyscrasias (abnormal or imbalance in blood components), liver damage or any symptom that may occur particularly to you
- if you are an elderly patient with dementia and are also taking risperidone.

Other medicines and FRUSEMIDE 250 mg/25 ml FRESENIUS

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

Please tell your doctor, pharmacist or healthcare provider if you are taking any of the following medicines as they may interact with **FRUSEMIDE 250 mg/25 ml FRESENIUS**:

- Antibiotics, e.g. tetracyclines, cephalosporins (e.g. cefaclor, cefuroxime), polymyxins, vancomycin or aminoglycosides (e.g. neomycin and tobramycin); using these together may increase toxicity and/or affect your hearing.
- Trimethoprim, used to treat certain bacterial infections, may cause low sodium levels.
- Medicines used to treat depression (e.g. tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs) or reboxetine).
- Medicines used to treat diabetics (high blood sugar).
- Heart medicines to help your heart beat (e.g. digoxin) or to help your heart beat regularly (e.g. sotalol, amiodarone, disopyramide, flecainide, lidocaine (lignocaine), tocainide, mexiletine).
- Medicines for mental disorder (e.g. pimozide, amisulpride, sertindole or phenothiazines, risperidone used to treat dementia).
- Medicines used to lower blood pressure (e.g. thymoxamine or hydralazine).
- Medicine used to pass more urine (e.g. metolazone).

- Medicine used to treat high blood pressure (e.g. thiazides (“water pills”) or aliskiren).
- Medicine used to prevent chest pain (angina) (e.g. nitrates).
- Medicines used to relax your muscles before or during surgery (e.g. atracurium).
- Medicines used for asthma (e.g. salbutamol).
- Sedatives, pain or sleeping tablets containing barbiturates.
- Narcotic type painkillers (e.g. codeine).
- Nonsteroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation (e.g. indomethacin or ketorolac).
- Salicylates used to treat moderate pain and inflammation (e.g. aspirin).
- Corticosteroids used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies and other conditions.
- Lithium – used to treat mood swings and some forms of depression.
- Sucralfate – used to treat and prevent ulcers in the intestines and may decrease the absorption of furosemide.
- Methotrexate – used to treat severe psoriasis, rheumatoid arthritis or certain cancers and may increase the chance of furosemide toxicity.
- Levodopa – used to treat Parkinson's disease and may increase the risk of lowering of blood pressure.
- Medicine used to treat gout (e.g. allopurinol or probenecid).
- Medicines to lower your blood pressure (e.g. angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor antagonists) as their effect may be enhanced.
- Medicines used for epilepsy (e.g. phenytoin).
- Medicines used to treat allergies (e.g. antihistamines).
- Medicines used to treat fungal infections (e.g. amphotericin – increased risk of potassium loss or renal damage).
- Medicines used to treat anxiety (chloral hydrate or triclorfos).
- Medicines used to treat attention deficit hyperactivity disorder (ADHD) (e.g. atomoxetine or amphetamines).

- Liquorice (increased risk of loss of potassium).
- Medicine used to treat cancers (e.g. cisplatin – increased the risk of kidney damage).
- Medicines that modify immune system (e.g. aldesleukin, ciclosprorin or tacrolimus).
- Medicines used as muscle relaxants (e.g. baclofen, tizanidine or curare-like muscle relaxants).
- Medicines used to treat erectile dysfunction (impotency) (e.g. alprostadil).
- Birth control pills or oestrogen-containing medicines may block the effect of furosemide, as in **FRUSEMIDE 250 mg/25 ml FRESENIUS**.
- Progesterone-containing medicines (e.g. drosperidone) may lead to increased blood potassium levels.
- Theophylline used to treat asthma (wheezing or difficulty in breathing).
- Medicines used as general anaesthetics (to induce unconsciousness). If you are going to receive an anaesthetic, please ensure that the anaesthetist or healthcare provider knows you are being given **FRUSEMIDE 250 mg/25 ml FRESENIUS**.
- Laxatives used to relieve constipation (e.g. bisacodyl or senna).

The maximum recommended daily dose of this product contains 363 mg sodium (found in table salt). This is equivalent to 18 % of the adult recommended maximum daily dietary intake for sodium. Talk to your phatrmacist or doctor if you need **FRUSEMIDE 250 mg/25 ml FRESENIUS** on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planinng to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving **FRUSEMIDE 250 mg/25 ml FRESENIUS**.

FRUSEMIDE 250 mg/25 ml FRESENIUS crosses the placenta and also appears in breast milk; it also reduces your blood volume. It should not be used if you are pregnant or if you breastfeed your baby (see also "**You should not be administered FRUSEMIDE 250 mg/25 ml FRESENIUS**").

Driving and using machines:

FRUSEMIDE 250 mg/25 ml FRESENIUS may make you feel dizzy and affect your vision. Do not drive a vehicle or use tools or machines if you are affected by the administration of **FRUSEMIDE 250 mg/25 ml FRESENIUS**.

3. How to receive FRUSEMIDE 250 mg/25 ml FRESENIUS

FRUSEMIDE 250 mg/25 ml FRESENIUS is normally administered in hospital, by a doctor or healthcare provider. Your doctor will tell you how long your treatment with **FRUSEMIDE 250 mg/25 ml FRESENIUS** will last.

Your doctor will decide what dose you should receive.

FRUSEMIDE 250 mg/25 ml FRESENIUS is normally given as an intravenous infusion over an hour. Depending on the volume of urine produced, the dose may be increased, and the infusion continued.

FRUSEMIDE 250 mg/25 ml FRESENIUS can also be slowly injected directly into a vein intravenously).

If you are given more FRUSEMIDE 250 mg/25 ml FRESENIUS than you should receive:

Since a healthcare provider will administer **FRUSEMIDE 250 mg/25 ml FRESENIUS**, he/she will control the dosage. In the event of overdosage, consult your doctor or pharmacist, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

FRUSEMIDE 250 mg/25 ml FRESENIUS can have side effects.

Not all side effects reported for **FRUSEMIDE 250 mg/25 ml FRESENIUS** are included in this leaflet.

Should your general health worsen of if you experience any untoward effects while being given

FRUSEMIDE 250 mg/25 ml FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving FRUSEMIDE 250 mg/25 ml FRESENIUS and tell your doctor 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 **FRUSEMIDE 250 mg/25 ml FRESENIUS**. You may need urgent medical attention.

Tell your doctor immediately if you notice the following:

Less frequent:

- Skin rash.
- Less urine than is normal for you.
- Change in the way your heart beats, for example, if it starts beating fast or slow.
- Hearing problems, such as deafness or ringing in the ears.
- Heart rhythm disturbances.

Frequency unknown:

- Yellowing of the eyes or skin, stomach pain, nausea, dark coloured urine – these may be signs of jaundice.

Tell your doctor as soon as possible if you experience any of the following:

Less frequent:

- Paraesthesia (feeling of tingling, prickling, tickling, burning or numbness of the skin with no apparent reason).
- Nausea (feeling sick), vomiting (being sick), diarrhoea, constipation, sudden inflammation of

the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.

- Skin sensitivity to light (photosensitivity).
- Abnormal blood count (white blood cell deficiency) accompanied by an increased susceptibility to infection.
- Increase in certain substances (eosinophilic cells) in the blood.
- In the case of severe potassium deficiency: interference with the function of the intestine or confusion which can result in coma.
- Lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright.
- Inflammation of blood vessels (vasculitis), including fever, headache, fatigue, weight loss, general aches and pains).
- Severe skin reactions such as itching, skin rash with severe itching and nettle rash, fever, sensitive to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, acute generalised exanthematous pustulosis (AGEP), DRESS, (acute febrile drug eruption) characterised by severe acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin.
- Raised blood levels of creatinine and urea as determined by blood tests.

Frequency unknown:

- Lack of energy, drowsiness, weakness, muscle cramps, restlessness, dehydration, dry mouth and thirst – these may be signs of a disturbance in the balance of electrolytes (salts) in your blood.
- Blurred or yellow vision.
- Dizziness, headache.
- Skin sensitivity to light (photosensitivity).
- Low blood pressure which may cause dizziness when standing up.
- Gout attacks (aching or swollen joints).

- Diabetes (high levels of sugar in your blood and urine).
- Hypovolaemic shock (a life-threatening condition caused by excessive loss of fluid, such as vomiting or diarrhoea).
- Bullous pemphigoid (an acute or chronic autoimmune skin disease, involving the formation of blisters, more appropriately known as bullae, in the space between the skin layers).
- The development of kidney stones in premature infants.

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 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 **FRUSEMIDE 250 mg/25 ml FRESENIUS**.

5. How to store FRUSEMIDE 250 mg/25 ml FRESENIUS

- Store in the original outer packaging at or below 30 °C, protect from light.
- Store all medicines out of reach of children.

6. Contents of the pack and other information

The active ingredient is furosemide.

Each 25 ml ampoule contains 250 mg furosemide.

The other ingredients are: Hydrochloric acid (for pH-adjustment), sodium chloride, sodium hydroxide, water for injection.

What FRUSEMIDE 250 mg/25 ml FRESENIUS looks like and contents of the pack:

A clear colourless solution in 25 ml amber type I glass ampoules, packed in boxes of 10.

Holder of Certificate of Registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten, 6020

Gqeberha

South Africa

Tel: 041 403 1600

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