

Approved Patient Information Leaflet for Frusemide 20 mg/2 ml Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

FRUSEMIDE 20 mg/2 ml FRESENIUS solution for injection or infusion

Furosemide

Sugar free.

Read all of this leaflet carefully before you are given FRUSEMIDE 20 mg/2 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 20 mg/2 ml FRESENIUS is and what it is used for
2. What you need to know before you are given FRUSEMIDE 20 mg/2 ml FRESENIUS
3. How to receive FRUSEMIDE 20 mg/2 ml FRESENIUS
4. Possible side effects
5. How to store FRUSEMIDE 20 mg/2 ml FRESENIUS
6. Contents of the pack and other information.

1. What FRUSEMIDE 20 mg/2 ml FRESENIUS is and what it is used for

The active ingredient, furosemide, belongs to a group of medicines called diuretics. It works in your kidneys to increase the amount of urine produced.

FRUSEMIDE 20 mg/2 ml FRESENIUS may be used to treat swelling of the ankles, feet, legs, brain, heart or lungs.

2. What you need to know before you are given FRUSEMIDE 20 mg/2 ml FRESENIUS

You should not be administered FRUSEMIDE 20 mg/2 ml FRESENIUS:

- if you are hypersensitive (allergic) to furosemide, sulphonamides or any of the other ingredients of FRUSEMIDE 20 mg/2 ml FRESENIUS (see section 6)
- if you have increased uraemia (high levels of waste products, normally excreted in the urine) and oliguria (urinate less than usual) during treatment of severe progressive kidney disease
- if your kidneys are failing or have stopped working due to liver coma
- if you have low levels of potassium or sodium salts or an imbalance of chemicals in your blood (shown in a blood test)
- if your blood volume is low (you may feel dizzy or faint or have pale skin) or if you are dehydrated
- if you have low blood pressure (dizziness or light-headedness)
- if you are unable to pass urine (anuria)
- if you previously received certain medicines that have damaged your kidneys or liver
- if you have severe liver problems (cirrhosis), affecting your consciousness
- 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 breastfeeding your baby (see section 4.6).

Warnings and precautions

Special care should be taken with FRUSEMIDE 20 mg/2 ml FRESINIUS

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

- if you have kidney problems or difficulty passing urine (for example caused by a large prostate gland)
- if you have low blood pressure (hypotension)
- if you have liver problems
- if you are currently taking antibiotics (e.g. cephalosporins or aminoglycosides)
- if you have diabetes
- if you have gout
- if you are an elderly person who also takes risperidone
- if you are on a low sodium diet, as you may lose too much water and get low blood pressure.

You should also know that:

- 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)
- kidney stones may form in babies born early (see section 4)
- your doctor may order laboratory tests to know if your blood electrolytes (salts) are balanced.

Other medicines and FRUSEMIDE 20 mg/2 ml FRESINIUS

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

Tell your doctor, pharmacist or healthcare provider if you are taking any of the following medicines:

- antibiotics, e.g. tetracyclines, cephalosporins (e.g. cefaclor, cefuroxime) or aminoglycosides (e.g. neomycin and tobramycin)
- antifungal medicines such as amphotericin
- heart medicines to help your heart beat (e.g. digoxin) or to help your heart beat regularly (such as amiodarone, sotalol)
- lithium – this medicine may be used to treat mood swings and some forms of depression
- risperidone used in elderly persons with dementia
- laxatives
- medicines for diabetes
- cancer medicines, such as cisplatin
- certain antihistamines
- medicines used to relax your muscles before or during surgery (such as atracurium)
- ciclosporin (may be used to prevent organ rejection)
- muscle relaxants such as tubocurarine
- medicines for depression (such as reboxetine)
- nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation
- sedatives, pain or sleeping tablets containing barbiturates
- narcotic type painkillers e.g. codeine
- corticosteroids
- medicines for stomach ulcer healing (such as ranitidine)
- medicines to lower your blood pressure, as their effect may be enhanced
- medicines used for epilepsy (such as carbamazepine, phenytoin)
- warfarin (to thin your blood).

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 planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving FRUSEMIDE 20 mg/2 ml FRESSENIUS.

FRUSEMIDE 20 mg/2 ml FRESSENIUS 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 20 mg/2 ml FRESSENIUS**”).

Driving and using machines

FRUSEMIDE 20 mg/2 ml FRESSENIUS may make you feel dizzy and affect your ability to concentrate. Do not drive or use tools or machines if you are affected by the administration of FRUSEMIDE 20 mg/2 ml FRESSENIUS.

3. How to receive FRUSEMIDE 20 mg/2 ml FRESSENIUS

You will not be expected to give yourself FRUSEMIDE 20 mg/2 ml FRESSENIUS.

It will be given to you by a person who is qualified to do so.

FRUSEMIDE 20 mg/2 ml FRESSENIUS is normally administered in hospital, by a doctor or healthcare provider. Your doctor will tell you how long your treatment with FRUSEMIDE 20 mg/2 ml FRESSENIUS will last.

Your doctor will decide what dose you should be given and how many times the dose must be repeated.

FRUSEMIDE 20 mg/2 ml FRESSENIUS is normally given into a vein (intravenously) or into a muscle (intramuscularly).

If you are given more FRUSEMIDE 20 mg/2 ml FRESENIUS than you should receive

Since a healthcare provider will administer FRUSEMIDE 20 mg/2 ml FRESENIUS, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

FRUSEMIDE 20 mg/2 ml FRESENIUS can have side effects.

Not all side effects reported for FRUSEMIDE 20 mg/2 ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given FRUSEMIDE 20 mg/2 ml FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving FRUSEMIDE 20 mg/2 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 20 mg/2 ml FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately if you notice the following:

- yellowing of the eyes or skin, stomach pain, nausea; dark coloured urine; these may be signs of jaundice or inflammation of the pancreas

- pain on the kidneys, blood in the urine and fever
- change in the way your heart beats, for example, if it starts beating faster or slower
- severe skin conditions such as bullous lesion, acute generalised exanthematous pustulosis (AGEP) and drug rash with eosinophilia syndrome (characterised by severe allergic reaction, accompanied by fever and blisters on the skin, peeling of the skin and tiny spots from bleeding in the skin).

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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
- metabolic acidosis (characterised by chest pain, irregular heartbeat, nausea, vomiting or unusual weakness/tiredness).

Less frequent side effects:

- skin rash and sensitivity to light (photosensitivity)
- gout attacks (aching or swollen joints), an abnormally high level of uric acid in the blood (hyperuricaemia)
- headache, paraesthesia (feeling of tingling, burning or numbness of the skin with no apparent reason), fainting
- high blood sugar
- high levels of sugar in your urine (glycosuria) which is characterised by extreme hunger, extreme thirst or dehydration, accidental urination or more frequent urination
- passing urine more often than normal (leading to an excessive depletion of body fluids and calcium)

- hypovolaemia (when the liquid portion of your blood (plasma) is too low, caused by vomiting, diarrhoea or excessive bleeding), dehydration (especially if you are elderly, characterised by increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats)
- dizziness, headache, paraesthesia (an abnormal sensation, typically tingling or prickling), syncope (loss of consciousness caused by a fall in blood pressure)
- low blood pressure which may cause dizziness when standing up
- bone marrow depression (a decrease in bone marrow activity, resulting in reduced production of blood cells)
- serious blood problems (characterised by bruising more easily or bleeding, getting more infections (e.g. sore throat, mouth ulcers, fever), feeling weak or tired more than usually).

Frequency not known:

- blurred or yellow vision
- hearing problems, such as deafness or ringing in the ears
- muscle pain and cramps or spasms
- nausea (feeling sick), vomiting, diarrhoea
- tiredness, irritated skin, pain at the injection site and fever
- stomach pain, nausea and vomiting (pancreatitis)
- a heart defect in premature babies found in the days or weeks after birth (patent ductus arteriosus)
- inflammation of blood vessels (vasculitis)
- difficulty urinating and completely emptying your bladder (if you have a bladder emptying disorder, an enlarged prostate gland or restricted urinary flow)
- low levels of thiamine (vitamin B1) (characterised by loss of appetite, weakness, pain in the limbs, shortness of breath and swollen feet or legs)
- high levels of cholesterol or triglycerides (fats) in your blood.

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

Reporting of side effects:

Health care providers are asked to report any suspected Adverse Drug Reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **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 20 mg/2 ml FRESENIUS.

5. How to store FRUSEMIDE 20 mg/2 ml FRESENIUS

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

6. Contents of the pack and other information

The active substance is furosemide. Each 1 ml contains 10 mg furosemide.

The other ingredients are hydrochloric acid 37 % (for pH-adjustment), sodium hydroxide, water for injection.

What FRUSEMIDE 20 mg/2 ml FRESENIUS looks like and contents of the pack:

FRUSEMIDE 20 mg/2 ml FRESENIUS is packed in 2 ml amber type I glass ampoules in packs of 10.

A colourless or almost colourless solution in 2 ml amber ampoules.

Holder of Certificate of Registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

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