

Frusemide Sandoz® Injection

frusemide injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Frusemide Sandoz Injection.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may want to read it again.

WHAT FRUSEMIDE SANDOZ INJECTION IS USED FOR

This medicine is used to reduce oedema (swelling) by removing the excess fluid from the swollen areas. It is also used to treat hypertension (high blood pressure) either alone or in combination with other drugs.

It contains the active ingredient frusemide which is also known as furosemide in some countries.

Frusemide belongs to a group of medicines called diuretics (“fluid tablets”)

It works in your kidneys by increasing the amount of urine produced. This reduces the amount of excess fluid in the body.

Ask your doctor if you have any questions about why Frusemide Sandoz Injection was prescribed for you.

Your doctor may have prescribed Frusemide Sandoz Injection for another reason.

This medicine is not addictive.

This medicine is available only with a doctor’s prescription.

BEFORE YOU USE FRUSEMIDE SANDOZ INJECTION

When you must not use it

Do not use this medicine if you have an allergy to:

- frusemide, the active ingredient or any of the inactive ingredients listed at the end of this leaflet under Product Description
- any other similar medicines, such as diuretics
- medicines containing sulfonamides, such as sulphur antibiotics or sulfonyleureas medicines used to treat diabetes.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use this medicine if you have or have had any of the following medical conditions:

- kidney problems or have no production or passing of urine

- liver problems
- low blood pressure
- low sodium or potassium levels in your blood
- dehydration.

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breastfeed if you are using this medicine.

The active ingredient in Frusemide Sandoz Injection passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to children unless your doctor has prescribed it.

If the medicine is for a newborn, tell your doctor if your baby had jaundice.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a severe imbalance in your electrolytes (the salts in your body)
- diabetes
- asthma
- kidney problems

- reduced passing of urine, difficulty passing urine, no production or no passing of urine
- heart and lung problems
- liver problems
- gout, a disease with painful, swollen joints
- prostate problems
- systemic lupus erythematosus (SLE), a disease affecting the skin, joints and kidneys
- high cholesterol levels

If you have not told your doctor about any of the above, tell him/her before you start using Frusemide Sandoz Injection.

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Frusemide Sandoz Injection may interfere with each other. These include:

- digoxin and other medicines used to treat heart failure
- lithium, used to treat mood disorders and some types of depression
- non-steroidal anti-inflammatory drugs (NSAIDs) and aspirin, used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- medicines used to treat high blood pressure and some other heart conditions, especially ACE inhibitors or angiotensin receptor antagonists certain antibiotics, especially cephalosporin
- medicines used to relax muscle before or during surgery
- amphotericin, used to treat fungal infections
- anticonvulsant medicines used to treat epilepsy, e.g. chloral hydrate or phenytoin

- sucralfate or carbenoxolone, used to treat stomach ulcers
- cisplatin, used to treat cancer
- steroid medicines, such as cortisone, prednisone or dexamethasone
- insulin and tablet medicines used to treat diabetes, e.g. metformin
- fluid tablets or diuretic medicines
- pressor amines, used in emergency situations e.g. adrenaline and noradrenaline
- barbiturates medicine used to treat epilepsy, to produce calmness, or to help you sleep
- narcotics/strong pain killers such as codeine and morphine
- theophylline, a medicine used to treat asthma
- medicines used during scans to see the images of your body.

These medicines may be affected by Frusemide Sandoz Injection, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW TO USE FRUSEMIDE SANDOZ INJECTION

Your doctor will decide what dose and how long you will receive Frusemide Sandoz Injection. This depends on your condition and how you react to this medicine.

Frusemide Sandoz Injection should only be given by a nurse or doctor. It can be given as an injection into your veins or your muscles.

If you are given too much

As Frusemide Sandoz Injection is given under medical supervision, it

is very unlikely that you will receive too much.

However, if you experience severe side effects after being given Frusemide Sandoz Injection, tell your doctor or nurse immediately.

Overdosage of Frusemide Sandoz Injection can result in dehydration. Symptoms of dehydration include dizziness, excessive thirst and dry mouth, headache and visual disturbances, weakness, muscle cramps and a fast heart beat.

WHILE YOU ARE USING FRUSEMIDE SANDOZ INJECTION

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Frusemide Sandoz Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are using this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests such as check your blood pressure from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you feel Frusemide Sandoz Injection is not helping your condition.

Tell your doctor if you have severe vomiting or diarrhoea.

Frusemide Sandoz Injection works by increasing the excretion of certain salts (sodium, chloride, potassium, etc) in your body. It is possible that you may lose too much salt. Your doctor may ask you to take a potassium supplement. It is best not to follow a diet that is too low in salt – **inform your doctor if you are on a low salt diet.** The signs that you are too low in body salts include: dry mouth, thirst, muscle weakness or cramps, fainting, passing less urine than normal, drowsiness, tiredness and a fast or irregular heartbeat. **If you experience these symptoms contact your doctor immediately.**

Make sure you drink enough water in hot weather and during exercise while you are using Frusemide Sandoz Injection, especially if you sweat a lot.

If you do not drink enough water, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly and you are losing too much fluid. **If you continue to feel unwell, contact your doctor.**

Things you must not do

Do not use Frusemide Sandoz Injection to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Frusemide Sandoz Injection affects you.

This medicine may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are using this medicine.

If you drink alcohol, dizziness and light-headedness may be worse.

It is not recommended that you drink alcohol while using Frusemide Sandoz Injection.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Be careful getting up from a sitting or lying position. Dizziness, light-headedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Avoid prolonged exposure to direct sunlight.

Frusemide Sandoz Injection may cause your skin to become more sensitive to the sun. If this happens you should wear protective clothing including a hat and sun screen when you are outside.

If you are taking Frusemide Sandoz for a long period of time, you should check with your doctor to determine whether or not you should eat more potassium-containing foods or take potassium supplements. However, increasing the amount of potassium in your diet may not be necessary and could be harmful. Check with your doctor.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Frusemide Sandoz Injection.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- headache
- fever

- dizziness or light-headedness
- very dry mouth or unusual thirst
- weight loss
- weakness, tiredness, drowsiness or lack of energy
- blurred or visual impairment
- unusual bleeding or bruising under the skin
- ringing or buzzing in the ears
- confusion
- nausea, vomiting, diarrhoea
- numbness or tingling in the hands or feet
- calf muscle spasms
- muscle pains or cramps
- restlessness

These are the more common side effects of Frusemide Sandoz Injection. Mostly, these are mild and are short-lived.

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

- irregular or fast heartbeat
- passing less urine than is normal for you
- loss of control of bladder or bowels (incontinence)
- severe dizziness or a spinning sensation
- increased sensitivity to sunlight
- flaking or peeling of the skin
- gout, a disease with painful, swollen joints
- deafness or ringing or buzzing in the ears
- severe stomach pain with nausea and vomiting
- increased frequency of infections, i.e. sore throat, fever, severe chills or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- symptoms of anaemia such as, tiredness or weakness, shortness of breath when exercising, dizziness and looking pale.

These may be serious side effects of Frusemide Sandoz Injection. You may need urgent medical attention. Serious side effects are uncommon.

If any of the following happen, stop using Frusemide Sandoz Injection, and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives (pinkish, raised areas) on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- chest pain
- fainting or a rapid weak pulse
- red, often itchy spots similar to rash seen with measles which starts on the limbs and sometimes on the face and body. The spots may blister and may progress to form raised red, pale-centred marks. Those affected may have fever, sore throat, headache with or without diarrhoea.
- lockjaw
- yellowing of the eyes or skin (jaundice).

These are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER USING FRUSEMIDE SANDOZ INJECTION

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Visually inspect for particulate matter before it is used.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store Frusemide Sandoz Injection or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Frusemide Sandoz Injection
20mg/2mL - clear, colourless solution supplied in a brown glass ampoule. Ampoules are placed on a tray, in a cardboard box.

Available in packs of 5 ampoules.

Ingredients

Active Ingredient:

- Frusemide Sandoz Injection
20mg/2mL - 20mg frusemide in each ampoule.

Inactive Ingredients:

- sodium hydroxide
- sodium chloride
- water for injection.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
19 Harris Street
Pymont NSW 2009
Australia
Tel: 1800 634 500

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay

Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was revised in August 2012.

Australian Register Number
20mg/2mL injection: AUST R
106463 (ampoules)