

## Frusemide Sandoz®

frusemide tablets

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Frusemide Sandoz.

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 taking this medicine against the benefits it is expected to have for you.

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

**Keep this leaflet with the medicine.**

You may want to read it again.

#### WHAT FRUSEMIDE SANDOZ IS USED FOR

This medicine is used to reduce oedema (swelling) by removing the excess fluid from the swollen - of the ankles, feet, legs or even the brain or lungs. It is also used to treat hypertension (high blood pressure) either alone or in combination with other drugs.

It contains the active ingredient frusemide.

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 was prescribed for you.**

Your doctor may have prescribed Frusemide Sandoz for another reason.

This medicine is not addictive.

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

#### BEFORE YOU TAKE FRUSEMIDE SANDOZ

*When you must not take it*

**Do not take 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 which are 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 take 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
- Jaundice or history of jaundice in newborns or infants
- hepatic coma or precoma.

**Do not take this medicine if you are pregnant.**

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

**Do not breastfeed if you are taking this medicine.**

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

**Do not give this medicine to children.**

**Do not take 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 taking this medicine, talk to your doctor.**

*Before you start to take 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
- passing less urine than is normal for you
- 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 taking Frusemide Sandoz.**

*Taking 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 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
- methotrexate, a medicine used to treat arthritis and some types of cancer

- probenecid, a medicine used to treat gout
- medicines used in emergency situations such as adrenaline and noradrenaline
- medicines used to treat high blood pressure and some other heart conditions, especially ACE inhibitors or angiotensin receptor antagonists
- certain antibiotics, especially cephalosporin and aminoglycosides
- medicines used to relax muscle before or during surgery
- amphotericin, used to treat fungal infections
- levothyroxine, used to treat hypothyroidism
- 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
- risperidone, an antipsychotic medication used to treat schizophrenia
- medicines used during scans to see the images of your body.

These medicines may be affected by Frusemide Sandoz, 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 taking this medicine.

#### HOW TO TAKE FRUSEMIDE SANDOZ

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

*How much to take*

**Oedema (swelling)**

The usual dose is 20mg to 80mg (a half to two tablets) given as a single dose, once or twice daily. If given twice daily, 8am and 2pm are the suggested times to take Frusemide Sandoz. In some cases, up to 400mg (ten tablets) a day may be taken. Some people may only take Frusemide Sandoz on a few days per week (i.e. two to four consecutive days).

**Hypertension (high blood pressure)**

The usual starting dose is 40mg (one tablet)

twice daily. This will then be increased or decreased depending on the individual response to treatment. Your doctor may reduce or even cease other high blood pressure medication you may be taking.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Frusemide Sandoz may not work as well and your problem may not improve.

#### *How to take it*

Swallow the tablets with water on an empty stomach.

If you need to break Frusemide Sandoz, hold tablet with both hands and snap along break line.

#### *How long to take Frusemide Sandoz*

**Continue taking your medicine for as long as your doctor tells you.**

The dosage recommendation and duration of treatment will be determined for your specific condition by your doctor.

**Do not take any more than prescribed by your doctor.**

#### *If you forget to take it*

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**Do not take a double dose to make up for the dose you missed.**

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

#### *If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Frusemide Sandoz. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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

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## WHILE YOU ARE USING FRUSEMIDE SANDOZ

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### *Things you must do*

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

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

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

It may affect other medicines used during surgery.

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

**If you are about to have any blood tests, tell your doctor that you are taking 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 is not helping your condition.

**Tell your doctor if you have severe vomiting or diarrhoea.**

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 taking Frusemide Sandoz, 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 take Frusemide Sandoz 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 taking 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 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 taking this medicine.**

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

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

**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 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.

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## SIDE EFFECTS

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

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. 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 often 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. You may need urgent medical attention. Serious side effects are uncommon.

**If any of the following happen, stop taking Frusemide Sandoz, 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.

- maize starch
- sodium starch glycollate
- lactose monohydrate
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

#### *Supplier*

Sandoz Pty Ltd  
 ABN 60 075 449 553  
 54 Waterloo Road  
 Macquarie Park NSW 2113  
 Australia  
 Tel: 1800 634 500

Novartis New Zealand Limited  
 PO Box 99102  
 Newmarket, Auckland 1149  
 New Zealand  
 Tel: 0800 354 335

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#### **Australian Register Number**

40mg tablets: AUST R 64718 (bottles)

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## AFTER USING FRUSEMIDE SANDOZ

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### *Storage*

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

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

Do not store Frusemide Sandoz 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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## PRODUCT DESCRIPTION

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### *What it looks like*

Frusemide Sandoz 40mg - round, white tablets with a score notch on one side.

Available in bottles of 100 tablets.

### *Ingredients*

Active ingredient:

- Frusemide Sandoz 40mg - 40mg frusemide.

Inactive ingredients:

- microcrystalline cellulose