

Approved Patient Information Leaflet for Medicines for Human Use:

SISERUP

SCHEDULING STATUS: S3

SISERUP 20 mg Tablet

SISERUP 40 mg Tablet

Furosemide

Contains sugar: lactose monohydrate

SISERUP 20 mg contains 52,50 mg lactose monohydrate.

SISERUP 40 mg contains 105,00 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking SISERUP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SISERUP 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 SISERUP is and what it is used for
2. What you need to know before you take SISERUP
3. How to take SISERUP
4. Possible side effects
5. How to store SISERUP
6. Contents of the pack and other information

1. What SISERUP is and what it is used for

The active ingredient in SISERUP is furosemide.

SISERUP is one of a group of medicines called diuretics (water tablets).

Your doctor has prescribed SISERUP to treat a condition called oedema where there is too much water in your body. This could be due to problems with your heart, lungs, kidneys, liver, blood vessels or high blood pressure. Furosemide helps your kidneys to get rid of the extra water that is not needed in your body.

2. What you need to know before you take SISERUP

Do not take SISERUP

- if you are hypersensitive (allergic) to furosemide, sulphonamides or any of the other ingredients of SISERUP (listed in section 6).
- if you have severe kidney damage which has stopped them working properly and producing urine
- if you are pregnant or may think you are pregnant or planning to get pregnant
- if you are breastfeeding
- if you have very low levels of potassium, sodium or other electrolytes in your blood or low blood volume (your doctor will be able to advise you)
- if you are dehydrated
- if you have low blood pressure
- if you take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. amiloride or spironolactone)
- if you have liver cirrhosis (tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) or liver

encephalopathy (confusion, altered levels of consciousness and coma as a result of liver failure)

- if you have Addison's disease (low levels of corticosteroid hormones secreted)
- if you have digitalis poisoning (feeling or being sick, high levels of potassium in the blood, slow, fast or irregular heartbeats).

Warnings and precautions

Take special care with SISERUP

Talk to your doctor or pharmacist before taking SISERUP

- if you have low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- if you have low levels of protein in the blood (hypoproteinaemia) as a result of kidney damage
- if you suffer from liver congestion (slowed blood flow through the vessels) or other liver problems
- if you have kidney problems or may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage
- if you are elderly, if you are on other medications which can cause the drop of blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- if you are having prostate trouble or difficulty passing urine or if have had gout
- if you have an abnormal blood condition
- if you are about to undergo any blood or urine tests.

Other medicines and SISERUP

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

- Medicines to lower blood pressure, such as ACE inhibitors, renin inhibitors, alpha blockers, calcium channel blockers, diuretics phenothiazines. SISERUP may potentiate their effect.
- Medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin. SISERUP may potentiate their effect.
- Medicines to treat mental illness (e.g., pimozide, amisulpride, sertindole). Taking SISERUP with these medicines may cause heart problems.
- Medicines used for heart problems (e.g., digoxin, amiodarone, disopyramide, flecanaide and sotalol). Taking SISERUP with these medicines may make your heart problems worse.
- Moxisylyte (thymoxamine) used for treating Raynaud's syndrome. SISERUP may potentiate its effect.
- Hydralazine used for treating angina. SISERUP may potentiate its effect.
- Lithium used for treating depression or mania. Taking SISERUP with lithium may cause lithium overdose.
- Sucralfate used for treatment of stomach ulcers since sucralfate reduces the absorption of furosemide and hence weakens its effect.
- Cholestyramine or colestipol used for treating high cholesterol. Taking these medicines concomitantly may cause furosemide toxicity.
- Medicines used to reduce inflammation (NSAIDs) such as indomethacin, acetylsalicylic acid may antagonise the action of SISERUP and may cause renal failure in case of pre-existing decreased volume of circulating blood in the body.

- Aspirin for treating pain or blood clotting. SISERUP may potentiate its effects.
- Antibiotics for infections (e.g., kanamycin, gentamicin, tobramycin), may affect your hearing and SISERUP may make this worse if taken together.
- Medicines for depression (such as lithium); medicines for asthma (such as theophylline, some muscle relaxants and aspirin related medicines. SISERUP may potentiate their effect.
- SISERUP may diminish the potency of medicines that control diabetes such as insulin.
- Medicine called phenytoin or carbamazepine used for epilepsy. SISERUP's effects may be affected by these medicines.
- Corticosteroids or antihistamines (to treat allergic reactions). Taking SISERUP with these medicines may affect your heart.
- Amphotericin (to treat fungal infections). SISERUP's effects may be affected by this medicine.
- Chloral hydrate (to treat insomnia). This medicine may cause furosemide toxicity.
- Medicines used for treating ADHD. Taking SISERUP with these medicines may cause heart problems.
- Medicines similar to furosemide such as metolazone, these medicines, when taken with SISERUP, may cause furosemide toxicity.
- Levodopa (for Parkinson's disease). This medicine may potentiate SISERUP's effects.
- Medicines treating cancer e.g., aldesleukin. This medicine may potentiate SISERUP's effect.
- Medicines used as muscle relaxants such as baclofen or tizanidine may potentiate SISERUP's effects.

- Medicines containing hormones such as oestrogen or progesterone often in oral contraceptives. These medicines may affect SISERUPS' effects.
- Alprostadil for erectile dysfunction. SISERUP's effects may be potentiated by this medicine.
- Certain treatments for asthma such as theophylline or salbutamol. These medicines may potentiate SISERUP's effects.
- Probenecid to prevent gout. Probenecid may cause furosemide toxicity and reduce SISERUP's effects.
- Alcohol may cause your blood pressure to fall when taken with SISERUP.
- Laxatives used over a long period of time. SISERUP effects may be potentiated with laxatives.
- Medicines or foods containing liquorice. SISERUP's effects may be affected by liquorice.
- If you are about to undergo a procedure where curariform muscle relaxants (e.g., vecuronium) or anaesthetics may be used, tell your anaesthetist/dentist or healthcare professional.

Pregnancy and breastfeeding

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 health care provider for advice before taking SISERUP.

SISERUP should not be taken by pregnant women or women who are breastfeeding.

Driving and using machines

Do not drive or operate machinery if you feel less alert after taking

SISERUP.

It is not always possible to predict to what extent SISERUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SISERUP affects them.

SISERUP contains lactose monohydrate

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Excipient sodium

SISERUP 20 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

SISERUP 40 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take SISERUP

Do not share medicines prescribed for you with any other person.

Always take SISERUP exactly as your doctor has told you.

If you are not sure, check with your doctor or pharmacist.

The usual starting dose for excess fluid is 20 mg (1 tablet of SISERUP 20 mg) to 80 mg (4 tablets of SISERUP 20 mg or 2 tablets of SISERUP 40 mg) in the morning. Your doctor may decide to increase your dose further if necessary.

Six hours after a 40 mg dose (1 tablet of SISERUP 40 mg or 2 tablets of SISERUP 20 mg), 80 mg (2 tablets of SISERUP 40 mg or 4 tablets of SISERUP

20 mg) may be taken and, if necessary, after another six hours, 120 mg (3 tablets of SISERUP 40 mg). After the oedema (e.g., swelling of limbs due too much water in your body) is controlled, maintenance therapy is continued at 20 mg (1 tablet of SISERUP 20 mg) to 40 mg (1 tablet of SISERUP 40 mg) daily. For doses exceeding 120 mg per day (more than 3 tablets of SISERUP 40 mg), it should be taken as 2 or 3 separate doses during the day.

The usual dose for the treatment of high blood pressure is 40 mg to 80 mg daily (1 – 2 tablets of SISERUP 40 mg). Your doctor may prescribe another medicine for high blood pressure, to be taken together with SISERUP 40 mg tablet.

Forced diuresis (increased excretion of urine e.g., used in management of barbiturate poisoning) 20 mg to 40 mg SISERUP (1 – 2 tablets of SISERUP 20 mg) is given in addition to infusion of electrolyte solution. Further treatment depends on the elimination of urine and must include substitution of the fluid and electrolyte losses. In poisoning with acid or basic substances the elimination rate can be further increased by alkalisation or acidification of the urine, respectively. This treatment will be managed by your doctor.

Infants and children under 15 years

Children generally receive an oral dose of 2 mg/kg body mass per day in divided doses. This may be titrated to a maximum of 6 mg/kg.

Method of administration

- SISERUP should be taken with a sufficient quantity of liquid (e.g. one glass of water)
- SISERUP should be taken at the same time every day, with or without food.

If you take more SISERUP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Symptoms of an overdose include dehydration and changes in the levels of certain chemicals in the blood.

If you forget to take SISERUP

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SISERUP can have side effects.

Not all side effects reported for SISERUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SISERUP, please consult your health care provider for advice.

If any of the following happens, stop taking SISERUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe allergic reaction which may include a skin rash, itching, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever could be a condition called Stevens-Johnson syndrome.
- Inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains) or kidney inflammation, this may change the

number of times you pass urine or you may see blood in your urine. You may have a fever, feel drowsy, or notice swelling e.g. of the ankles.

- Blood clot (causing pain, swelling or tenderness in the legs)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dehydration, altered balance of fluid or chemicals in the body (e.g. sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain, fatigue or cramps, low blood pressure causing loss of concentration and slowed reactions, difficulty passing water, fast or irregular heart rate and feeling and being sick.
- Low blood volume (hypovolaemia)
- Increased creatinine and blood urea (seen in blood tests)

Less frequent side effects:

- Anaemia causing tiredness, breathlessness, unusual bleeding or bruising
- Changes in the body seen in tests such as levels of cholesterol, glucose, uric acid
- Gout
- Changes in vision including blurred or yellow vision
- Light-headedness, sensations of pressure in the head, headache, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing.

- Irregular heartbeat
- Muscle cramps or weakness
- Changes in the amount or need to urinate
- Tiredness
- Dry mouth, thirst, feeling or being sick, changes in bowel movements including diarrhoea and constipation
- Deafness (sometimes irreversible)
- Changes in blood cells such as amount of white blood cells, reduction of platelets causing a rash fever, sweating, tiredness, and weight loss. Your doctor will perform regular blood tests to ensure no changes have occurred.
- Psychiatric disorder NOC causing delusions, hallucinations, disorganized speech
- Feeling 'pins and needles' or tingling sensation
- Confusion, headache, tiredness, generally feeling unwell, fever
- 'Ringing' in the ears, loss of hearing usually reversible
- Symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- Inflammation of the pancreas causing pains in your abdomen or back and nausea
- Changes in the liver causing yellowing of the skin or whites of the eyes
- Skin rashes
- Involuntary movements of the muscle
- Inflammation or failure of the kidney which may cause back pain or
- changes in the amount or need to urinate

Side effects with frequency unknown:

- Worsening of conditions where there is already balances of fluid or chemicals in the body
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- Decreased levels of potassium in the body

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 or 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 SISERUP.

5. How to store SISERUP

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blister packs in carton until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SISERUP contains

- The active substance is furosemide.

Dezzo Trading 392 (Pty) Ltd, 561244/5, SISERUP 20 mg and 40 mg Tablets

- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, sodium starch glycollate, magnesium stearate.

What SISERUP looks like and contents of the pack

SISERUP 20 mg and 40 mg are available in white opaque PVDC coated PVC / Aluminium blisters in pack sizes of 28's, 30's 56's 84's or 112's.

SISERUP 20 mg and 40 mg are available in white HDPE jars in pack sizes of 250's, 500's and 1000's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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