PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Furosemide 40 Biotech, capsule

Furosemide

Contains sugar (lactose 90 mg per capsule)

Read all of this leaflet carefully before you start taking Furosemide 40 Biotech

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or other healthcare provider.
- Furosemide 40 Biotech 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 Furosemide 40 Biotech is and what it is used for

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

Your doctor has prescribed Furosemide 40 Biotech capsules 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 40 Biotech 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 Furosemide 40 Biotech

Do not take Furosemide 40 Biotech if:

- you are allergic (hypersensitive) to furosemide, sulphonamides or any of the other ingredients in Furosemide 40 Biotech capsules (see section 6)
- you have elevated levels of urea and other nitrogen compounds in your blood
- you have a condition which is characterised by low blood volume (with or without low blood pressure)
- you have low levels of salts (potassium and sodium) in your blood
- you are dehydrated
- your urine output is below normal
- you have severe kidney damage which has stopped them working properly and producing urine
- 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)
- you are breastfeeding your baby.

Warnings and precautions

Take special care with Furosemide 40 Biotech if:

- you have low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- you have low levels of protein in your blood (hypoproteinaemia) as a result of kidney damage
- you have liver congestion (slowed blood flow through the vessels) or other liver problems
- you have kidney problems
- you may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage

- 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
- you have prostate trouble or difficulty passing urine
- you have had gout
- you have an abnormal blood condition
- you are to undergo any blood or urine tests.

Other medicines and Furosemide 40 Biotech

Always tell your healthcare 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
- medicines to treat mental illness (e.g., pimozide, amisulpride, sertindole)
- medicines for dysrhythmias (e.g., sotalol, amiodarone, flecainide)
- digoxin for your heart
- moxisylte for Raynaud's syndrome
- nitrates (for angina)
- lithium for depression or mania
- sucralfate for stomach ulcers
- cholestyramine or colestipol for high cholesterol
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g., ibuprofen or naproxen
- aspirin for pain
- antibiotics for infections that affect your kidneys or ears (e.g., cefaclor, colistin, gentamicin, vancomycin)
- antidepressants (e.g., monoamine oxidase inhibitors (MAOIs))
- medicines to control diabetes such as insulin or tablets

- antiepileptics e.g., phenytoin or carbamazepine
- amphotericin (to treat fungal infections)
- corticosteroids or antihistamines (to treat allergic reactions)
- chloral hydrate (to treat insomnia)
- medicines for ADHD
- medicines treating cancer e.g., aldesleukin
- levodopa (for Parkinson's disease)
- oral contraceptives
- alprostadil for erectile dysfunction
- certain treatments for asthma such as theophylline or salbutamol
- probenecid to prevent gout
- 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
- laxatives used over a long period of time
- medicines or foods containing liquorice

Furosemide 40 Biotech with food and drink

Furosemide 40 Biotech may cause an enhanced hypotensive effect.

Pregnancy, breastfeeding and fertility

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 taking this medicine.

Do not take Furosemide 40 Biotech if you are breastfeeding your baby.

Driving and using machines

You may experience reduced mental alertness.

It is not always possible to predict to what extent Furosemide 40 Biotech may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which Furosemide 40 Biotech affects you.

Furosemide 40 Biotech contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Furosemide 40 Biotech.

3. How to take Furosemide 40 Biotech

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

Always take Furosemide 40 Biotech exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose is 40 mg in the morning.

High blood pressure: 20 - 40 mg twice a day.
Children generally receive daily oral doses of 1 mg/kg body weight. If necessary, this dose may be increased step by step to a maximum of 3 mg/kg body weight per day. A dose of 120 mg per day should not be exceeded with children.

Your doctor will tell you how long your treatment with Furosemide 40 Biotech will last.
If you have the impression that the effect of Furosemide 40 Biotech is too strong or too weak, tell your doctor or pharmacist.

If you take more Furosemide 40 Biotech than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to take Furosemide 40 Biotech

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

4. Possible side effects

Furosemide 40 Biotech can have side effects.

Not all side effects reported for Furosemide 40 Biotech are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Furosemide 40 Biotech, please consult your healthcare provider for advice.

If any of the following happens, stop taking Furosemide 40 Biotech and tell your doctor immediately or go to the casualty department of your nearest hospital:

- 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 Furosemide 40 Biotech. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blood disorders, such as bone marrow depression
- cardiac dysrhythmia, a sudden drop in blood pressure when you stand from a seated or prone (lying down) position

- patent ductus arteriosus (PDA) is a persistent opening between the two major blood vessels leading from the heart of a baby

These are all serious side effects. You may need urgent medical attention.

Tel 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
- a condition that occurs when the level of sodium in the blood is too low
- low blood volume
- increased creatinine and blood urea (seen in blood tests)
- results from either low chloride intake or excessive chloride wasting
- too low calcium levels in the blood, too low magnesium in blood
- abnormally low level of the chloride ion in the blood
- light-headedness, sensations of pressure in the head, headache, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing.
- a kidney disorder in which an excess of calcium deposited in the kidneys
- creatinine increased
- blood urea increased

Less frequent side effects:

- blood disorders e.g., leukopenia, agranulocytosis, thrombocytopaenia
- anaemia causing tiredness, breathlessness, unusual bleeding or bruising
- gout
- changes in the body seen in tests such as levels of cholesterol, glucose uric acid

- 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
- dry mouth, thirst, feeling or being sick, changes in bowel movements including diarrhoea and constipation
- psychiatric disorder NOC causing delusions, hallucinations, disorganised speech
- feeling 'pins and needles' or tingling sensation
- confusion, headache, tiredness
- changes in vision including blurred or yellow vision
- deafness (sometimes irreversible)
- ringing in the ears, loss of hearing usually reversible
- symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- dry mouth, thirst, nausea, bowel motility disturbances, vomiting, diarrhoea and constipation
- 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
- photosensitivity, toxic epidermal necrolysis (TEN) is a rare and serious skin condition
- muscle cramps, weakness
- inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate
- worsening of conditions where there is already balances of fluid or chemicals in the body
- swelling in between the kidney tubules
- a condition in which the kidneys suddenly can't filter waste from the blood
- generally feeling tired, unwell, fever

The frequency of the following side effects is unknown:

- alkalosis involves a primary increase in serum bicarbonate (HCO3-) concentration,

- excretion of potassium
- dizziness, fainting and loss of consciousness
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- hives, various forms of dermatitis, allergic skin reactions
- a skin disorder characterised by bull's-eye-shaped lesions.
- a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters

If you notice any side effects not mentioned in this leaflet, please inform your doctor of 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 Furosemide 40 Biotech.

5. How to store Furosemide 40 Biotech

Store out of reach of children

Store at or below 25 °C in a cool place. Protect from light.

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What Furosemide 40 Biotech contains

Each capsule contains 40 mg of the active substance furosemide.

The other ingredients are colloidal silicon dioxide (Aerosil 200), purified talc and lactose.

The other ingredients are Elanco Opaque Blue 50, Brilliant Blue CI 42090 Erythrosine CI 45430, Elanco Opaque White, Gelatine, Titanium Dioxide CI 77891.

What Furosemide 40 Biotech looks like and contents of the pack

Opaque white body/opaque turquoise blue cap, size '2' snap-fit capsule containing white, lump-free powder.

Furosemide 40 Biotech capsules are available in transparent PVC/PVDC/ Aluminium blister packs of 30 capsules. Each blister strip contains 10 capsules, and 3 blister strips are packed in an outer carton.

White, opaque, round HDPE bottles with white, opaque PP CT cap with wad having induction sealing liner.

Pack size: 30, 100, 112, 250, 1 000

White HDPE securitainer with white LDPE tear-off cap and foam disc (wadding).

Pack size: 30, 100

Patient ready packs (PRP's) are available in pack sizes of 28, 56 or 84 capsules.

All pack sizes may not necessarily be marketed at one time.

Holder of Certificate of Registration

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