SCHEDULING STATUS: S3

BURINEX 1 mg, Tablets
Bumetanide
Contains sugar: Lactose 51,4 mg per tablet

Read all of this leaflet carefully before you start taking BURINEX

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

1. What BURINEX is and what it is used for

BURINEX is a type of medicine called a diuretic which increases the amount of water (urine) passed.

BURINEX is used to treat excess fluid accumulation in the body (oedema) which can be caused by heart, liver, lungs or kidney disease.

2. What you need to know before you take BURINEX

Do not take BURINEX:

- if you are hypersensitive (allergic) to bumetanide or any of the other ingredients of BURINEX (listed in section 6)
- are producing less urine than usual, or no urine at all
- suffer from severe liver disease, or are in a coma due to severe liver problems
- suffer from a severe imbalance of water and salts in the body.

Warnings and precautions

Take special care with BURINEX:

- if you are on a low salt diet
- if you know that you have severe (very low or very high) changes in your blood “salt” levels (sodium, potassium, chloride or bicarbonate)
- if you are taking BURINEX long-term, you should have a high potassium diet or taking potassium supplements or your doctor will prescribe another medicine such as

spironolactone

- if you are treated long-term with corticosteroids, you have ulcerative colitis, prolonged vomiting or diarrhoea
- if you have pre-existing liver impairment
- if you have low blood pressure
- if you suffer from gout
- if you have kidney problems
- if you have diabetes, or are at risk of developing diabetes (your doctor may have told you, for example, that you have higher than normal levels of sugar in the blood after eating)

Your doctor may give you regular blood and urine tests whilst you are taking BURINEX.

Children and adolescents
Not recommended for children.

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

- if you are taking medicines for diabetes
- cardiac glycosides e.g., digoxin
- if you are given non-depolarising neuromuscular blocking medicines that with cause hypokalaemia
- medicines for high blood pressure e.g., captopril, atenolol
- non-steroidal anti-inflammatory drugs e.g., aspirin, diclofenac
- lithium - used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- ototoxic medicines (which may affect hearing and balance) e.g. streptomycin or gentamicin
- medicines used to treat irregular heartbeat e.g. amiodarone, sotalol
- medicines that deplete blood potassium levels e.g. diuretics, laxatives
- probenecid - used to treat gout

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 health care provider for advice before taking BURINEX.

Do not take BURINEX if you are in the first 3 months of pregnancy or breastfeeding.

Driving and using machines
It is not always possible to predict to what extent BURINEX may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until

you are aware of the measure to which BURINEX affects you.

BURINEX contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BURINEX.

3. How to take BURINEX
Do not share medicines prescribed for you with any other person.

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

The usual dose is one 1 mg tablet per day taken in the morning or early evening. Your doctor may increase your dose and prescribe a second tablet 6 to 8 hours later.

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

If you take more BURINEX 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 BURINEX
Do not take / receive a double dose to make up for forgotten individual doses.

If you stop taking BURINEX
You should continue to take these tablets for as long as your doctor tells you to.

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

If any of the following happens, stop taking BURINEX and tell your doctor immediately or go to the casualty department at 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.

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

Tell your doctor if you notice any of the following:
Less frequent side effects:

- bone marrow depression, a condition in which there is impairment in blood cell production. This can result in anaemia, reduced ability to fight infection and bruising or bleeding

Side effects with unknown frequency:

- blood disorders including unusual bleeding or unexplained bruising
- electrolyte depletion such as low potassium, low sodium, low chloride levels in blood, a high level of the electrolyte potassium in the blood
- an excess of uric acid in the blood
- dehydration
- high levels of blood sugar
- hearing disturbances (reversible)
- low blood pressure
- stomach-ache or cramps, vomiting, nausea, indigestion or heartburn, diarrhoea
- inflamed pancreas (symptoms include upper abdominal pain, nausea and vomiting)
- patients with long term liver disease may develop encephalopathy, a disorder affecting the brain that may cause memory loss, changes in personality or fits and elevated levels of blood enzymes
- hives
- muscle cramps or spasms, joint pain
- painful breasts or, in men, breast enlargement
- swelling in the feet and ankles
- increase in the blood levels of urea and creatinine

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, 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 BURINEX.

5. How to store BURINEX
Store all medicines out of reach of children.
Store at or below 30 °C.
Protect from light.
Keep blisters in the carton until required for use.
Do not use after the expiry date stated on the label / carton.
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 BURINEX contains

- The active substance is bumetanide 1 mg.
- The other ingredients are agar powder, corn starch, lactose, magnesium stearate, polyethyleneglycol sorbitan oleate, polyvinylpyrrolidone, silicon dioxide and talc.

What BURINEX looks like and contents of the pack

BURINEX 1 mg tablets are white, flat (8 mm), circular, uncoated, bevelled edge tablet, marked on one face with a score line and with the number “133” on the other.

BURINEX 1 mg tablets are packed in PVC/Aluminium blisters. Cartons containing three (3) or ten (10) blister packs of 10 tablets each.

Holder of Certificate of Registration

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