

PACKAGE LEAFLET: INFORMATION FOR THE USER

Burinex® 0.5 mg/ml, solution for injection Bumetanide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Burinex 0.5mg/mL solution for injection will be called Burinex.

What is in this leaflet

1. What Burinex is and what it is used for
2. What you need to know before you use 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 available as a solution for injection, containing 0.5 mg bumetanide per ml.

Burinex® belongs to a group of medicine called diuretics.

Burinex® works by removing any excess water from your body. It will make you go to the toilet more.

Burinex is used:

- To treat high blood pressure, fluid retention (oedema) in the body, *e.g.* if you have disturbed heart function, if you have impaired renal function or if, for some other reason you need to increase the production of urine.
- To treat drug poisoning with salicylates (painkillers) or barbiturates (hypnotics).

2. What you need to know before you use Burinex®

Do not use Burinex

- if you are allergic to bumetanide, formaldehyde or any of the other ingredients in this medicine (listed in section 6).
- if you have been told that you have very low levels of potassium, sodium or chloride in your blood.
- if you cannot make urine at all.
- if you have severe liver problems or are in a coma caused by this (hepatic encephalopathy).

Warnings and precautions

Formaldehyde is a degradation product which occurs in Burinex in trace amounts during storage.

Because formaldehyde may cause a severe allergic reaction caution should be taken when Burinex is administered.

Talk to your doctor, pharmacist or nurse before using Burinex.

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Burinex or other sulphonamides, e.g., loop diuretics.
- If you have severe liver problems.
- If you have low blood pressure.
- If you have been told that you have abnormal levels of potassium in your blood. Your doctor may test your blood regularly.
- If you use drugs called proton pump inhibitors as this may cause magnesium in your blood to fall.
- If you have gout.
- If you suffer from kidney problems or a blockage of your kidney or bladder.
- If you suffer from diabetes. Your doctor may test your blood and urine regularly.
- If you are allergic (hypersensitive) to medicines called sulphonamides.

Serious skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in association with Burinex treatment. Stop using Burinex and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Burinex is banned for use in sports and will cause disqualification for sports persons as it will be detected in urine during routine tests.

Extra tests that may be required when taking Burinex

Most people taking Burinex will have regular tests to check the levels of water and other substances (in particular sodium, magnesium and potassium) in their blood.

If you are diabetic, you will have tests to check the amount of glucose in your blood and urine as Burinex can affect your glucose levels.

Children and adolescents

Do not give this medicine to children or adolescents because limited information is available and it is not known if it is safe to use.

Other medicines and Burinex

Tell your doctor pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription.

You must tell your doctor or pharmacist if you are taking any of the following:

- Medicines for heart conditions (e.g. digoxin), as they may make you feel or get sick or experience changes in your heart rate.
- Medicines that relax your muscles. If you are to be given a muscle relaxant (usually given by injection, before a general anaesthetic), please tell your hospital doctor that you are taking Burinex.
- Lithium, as Burinex will increase the lithium level in your blood and your dose may need to be changed.
- Medicines for heart conditions (e.g. amiodarone), as they may cause dizziness, confusion, muscle weakness, twitching, tiredness, confusion, a sudden loss of consciousness, very fast heart beat or heart attack.
- Non-steroidal anti-inflammatory drugs e.g. ibuprofen, for arthritis or aches and pains, as they may damage your kidneys.
- Medicines for high blood pressure, as they may make you dizzy.
- Medicines for depression (e.g. tricyclic antidepressants), as they may make you dizzy.
- Any medicine that affects the amount of potassium in your blood e.g. some diuretics.

- Medicines to treat certain bacterial infections (e.g. neomycin), as it might damage your hearing.
- Probenecid, a treatment for gout.
- Medicines for diabetes as your dose may need to be changed.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

This medicine should not be used in pregnancy unless clearly necessary. It may only be used in case your heart stops working and when the benefit outweighs the risk to the unborn child.

Tell your doctor if you become pregnant while taking this medicine.

Breast-feeding

Do not take this medicine if you are breast-feeding.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery. However, dizziness may occur when taking Burinex and this could affect you.

Check with your doctor if you get any side effects that may affect your driving or using machinery.

Burinex contains: Sodium

This medicinal product contains less than 23 milligrams (mg) in a dose of 5 milligrams, i.e. essentially “sodium-free”.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to take Burinex

Bumetanide will be given to you by a doctor or nurse. It may be given into your vein or into your muscle.

How much Burinex to have

Your doctor will prescribe the right dose for you.

You are likely to need the toilet more often after you have had your medicine.

Adults:

Accumulation of fluid in the lungs:

The usual dose for oedema affecting your lungs is 0.5-2 mg injected into a vein. You may be given another injection later if necessary.

If you are given this medicine by a drip into the vein the usual dose is 2 to 5mg. This may take between 30 to 60 minutes to give.

If you are given your injection into a muscle, the usual dose is 1mg.

Your doctor may change your dose depending on your test results.

Use in the elderly or patients with impaired liver or kidney function

Your doctor may prescribe less medicine than the usual dose to start with. Your doctor may then adjust your dose to make sure the dose is right for you.

Use in children

Burinex is not recommended for use in children.

If you have more Burinex than you should

Your doctor or nurse will give you this medicine. If you think you may have been given too much, tell your doctor or nurse straight away.

If you have missed a dose of Burinex

Your doctor or nurse will give you this medicine. If you think you have missed a dose then tell your doctor or nurse.

If you stop taking Burinex

Always ask your doctor if you wish to pause or stop receiving treatment with Burinex. Contact your doctor immediately if your symptoms get worse after treatment with Burinex is stopped.

If you have any further questions about having this medicine, please ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical trials, approximately 12 out of every 100 patients got a side effect.

Important side effects to look out for:

Stop using Burinex and seek medical attention immediately if you notice any of the following symptoms:

- **reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnson syndrome, toxic epidermal necrolysis].**

You must get medical help straight away if you have any of the following symptoms. You may be having a severe allergic reaction.

- You have difficulty breathing.
- Your lips and mouth start to tingle or swell.
- Your face or throat swell.
- Your skin develops a severe rash.

Important side effects that can also become serious. You should tell your doctor as soon as possible:

Common (may affect up to 1 in 10 people)

- Low potassium levels in your blood; possible signs of this are muscle weakness, twitching or an abnormal heart rate.
- Low sodium levels in your blood; this could cause tiredness, confusion, muscle twitching, fits or coma.
- High potassium levels in your blood which may cause an irregular heartbeat.

Uncommon (may affect up to 1 in 100 people)

- You may become more sensitive to light.
- You may pass little or no urine and your kidneys may stop working completely.
- Your may have problems with your bone marrow or blood, the signs of this are:
 - Feeling tired, dizzy, short of breath or looking pale.

- You may get infections more often such as a sore throat or mouth ulcers.
- You may bleed or bruise more easily than normal.

Other possible side effects which are usually less serious can occur:

Common (may affect up to 1 in 10 people)

- Low chloride levels in your blood; you usually will not notice this.
- Dizziness especially when standing up due to low blood pressure or problems with your balance (vertigo).
- You may feel sleepy, unusually weak, lack energy or have a general feeling of being unwell.
- Headache.
- You may feel sick, get pain or discomfort in your stomach.
- You may experience pain, aching muscles not caused by exercise and muscles spasms.
- You may need to go to the toilet very often, during the night or pass very large amounts or very small amounts of water (urine).

Uncommon (may affect up to 1 in 100 people)

- You may lose too much water from your body and feel tired and sick.
- You may have low or high sugar levels in your blood.
- The signs of low sugar levels are confusion, blurred vision, slurred speech, aggression, loss of consciousness, fast or irregular heartbeat, tremor, anxiety, sweating and hunger.
- The signs of high sugar levels are excessive thirst and hunger, needing to pass water (urine) often, blurred vision, sleepiness, weight loss and a dry mouth.
- You may experience high uric acid levels in your blood which may cause painful swollen joints (gout).
- Fainting.
- Problems with your hearing.
- Chest pain and discomfort.
- Low blood pressure. This might make you feel dizzy.
- Shortness of breath or a cough.
- Vomiting.
- Diarrhoea or constipation.
- Dry mouth or feel thirsty.
- Skin problems such as a rash with raised lumps or pimples, hives.
- Itching of the skin often including blisters that weep and become crusted.
- Swelling of hands ankles or feet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting:

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Burinex

- Store below 25°C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the packaging after “EXP”. The expiry date refers to the last day of the stated month.
- Store the ampoules in the outer packaging to protect against light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Burinex[®] 0.5 mg/ml solution for injection contains:

- The active ingredient is bumetanide 0.5 milligrams per millilitre.
- The other ingredients are disodium hydrogen phosphate dehydrate, sodium dihydrogen phosphate dihydrate, water for injections and xylitol.

What Burinex looks like and contents of the pack

Burinex is a clear, colourless solution. This medicine comes in amber glass ampoules.

Pack sizes:

- Carton box of 5 ampoules containing 2 ml each (= 1 mg bumetanide per ampoule)
- Carton box of 5 ampoules containing 4 ml each (= 2 mg bumetanide per ampoule)
- Carton box of 5 ampoules containing 10 ml each (= 5 mg bumetanide per ampoule)

Not all mentioned pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in