

Package leaflet: Information for the user

Burinex[®] 5 mg Tablets bumetanide

Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Burinex[®] 5 mg Tablets 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 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 5 mg tablets contain the active substance bumetanide. It is a diuretic (water tablet). It works by removing any excess water from your body. It will make you go to the toilet more often.

Burinex is used in adults to treat oedema which occurs as a result of heart, kidney or liver problems. Oedema means that there is too much water in parts of your body. Oedema can cause symptoms such as swollen ankles or trouble breathing.

2. What you need to know before you take Burinex[®]

Do not take Burinex

- If you are allergic (hypersensitive) to bumetanide 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 pass water (urine) at all.
- If you have severe liver problems or are in a coma caused by this (hepatic encephalopathy).

Warnings and precautions

Talk to your doctor or pharmacist before taking Burinex

- 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 are taking proton pump inhibitors as this may cause magnesium levels in your blood to fall.
- If you have gout.
- If you have kidney problems or a blockage of your kidney or bladder.
- If you have diabetes. Your doctor may test your blood and urine regularly.
- If you are allergic (hypersensitive) to medicines called sulphonamides.
- If you have an intolerance to lactose (please see the end of section 2).

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 (e.g. salts such as 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 or 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 for heart conditions (e.g. amiodarone), as they may cause dizziness, confusion, muscle weakness, twitching, tiredness, a sudden loss of consciousness, very fast heart beat or heart attack.
- Lithium, as Burinex will increase the lithium level in your blood and your dose may need to be changed.
- Non-steroidal anti-inflammatory drugs e.g. ibuprofen, for arthritis or aches and pains, as they may damage your kidneys.
- Medicines for depression (e.g. tricyclic antidepressants), as they may make you dizzy.
- Medicines for high blood pressure, as they may make you dizzy.
- Probenecid, a treatment for gout.
- Medicines to treat certain bacterial infections (e.g. neomycin), as it might damage your hearing.
- Medicines for diabetes as your dose may need to be changed.
- 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.
- Any medicine that affects the amount of potassium in your blood e.g. some diuretics.

Pregnancy, breast-feeding and fertility

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

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 lactose monohydrate. This is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Burinex®

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

How much Burinex to take

Your doctor will tell you how many tablets to take. You should take the tablets in the morning. This will help to stop you getting up in the night to go to the toilet. To remind you to take your medicine, it may help to take it when you do another regular activity such as brushing your teeth.

Remember to always take this medicine with a glass of water.

If you are taking more than one tablet a day, you may be told to take them in two or more doses.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Adults

- To treat oedema:

The recommended starting dose for Burinex 5 mg Tablets is 1 tablet a day.

Your doctor may change your dose depending on how the medicine works for you.

If you take more Burinex than you should

Tell your doctor straight away. You may need to stop taking this medicine. Signs that you have taken too much include dry mouth, thirst, weakness, drowsiness, muscle pain and confusion. You may also feel sick or pass a very large amount of water (urine) e.g. 2-3 litres.

If you forget to take Burinex

If the dose is less than 12 hours late, take it immediately. If it is more than 12 hours late, leave it out. Take your next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you keep forgetting to take your tablets, speak to your doctor.

If you have any further questions on the use of this medicine, please ask your doctor or pharmacist.

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:

Although allergic reactions are not known to happen with Burinex, it could happen with any medicine. 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.
- You 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 muscle 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2;

Tel: +353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail:

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

5. How to store Burinex[®]

- 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 carton and blister (EXP). This expiry date refers to the last day of that month.
- Keep the blisters in the outer carton in order to protect from light.
- Burinex 5 mg Tablets: Store below 25°C.

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 contains

- The active substance is bumetanide.
- The other ingredients are: maize starch, lactose monohydrate, colloidal anhydrous silica, povidone, polysorbate 80, agar powder, talc and magnesium stearate.
- You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What Burinex looks like and contents of the pack

Burinex 5 mg Tablets are a white, flat, circular, uncoated, bevelled edge tablet marked with a score line and '5 mg' on one face.

Burinex comes in blister packs of 30 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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