

Burinex[®] **(bue-rin-ex)** **Bumetanide 1 mg tablets**

Consumer Medicine Information (CMI)

Please read this leaflet carefully before you start your treatment.

Keep this leaflet. You may want to read it again.

What is in this leaflet?

This leaflet answers some of the common questions about Burinex[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Burinex[®] against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What Burinex[®] is used for?

Burinex[®] is a medicine which makes the kidneys produce more urine. It is effective for people who have swollen feet and ankles due to fluid which has built-up as a result of heart, liver or kidney disease. It is also used when there is too much fluid in the lungs.

Burinex[®] belongs to a group of medicines called diuretics.

Your doctor may have prescribed Burinex[®] for another reason. Ask your doctor why Burinex[®] has been prescribed for you.

Burinex[®] is only available with a doctor's prescription.

There is no evidence that Burinex[®] is addictive.

Before you use Burinex[®]

When you must not use Burinex[®]

Do not use Burinex[®] if you:

- have ever had an allergic reaction to Burinex[®] (bumetanide) or to any ingredients listed at the end of this leaflet
- have kidneys that are so diseased they are unable to produce urine
- are dehydrated or short of essential simple chemicals in your blood
- disease of the brain caused by liver illness including coma

Do not use Burinex[®] after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not be as effective.

Do not use Burinex[®] if the packaging is torn, doesn't look quite right or shows signs of tampering.

If any of these apply, return the medicine to your pharmacist for disposal.

Do not use Burinex[®] to treat any other complaints without your doctor's permission.

Do not give Burinex[®] to anyone else even if they have the same condition as you.

Before you start to use Burinex®

Tell your doctor if you:

- have an allergy to Burinex® (bumetanide), to any of the ingredients listed at the end of this leaflet or to a 'sulpha' (sulphonamide) medicine which is an antibiotic, other antibiotics, or some medicines for diabetes
- have some symptoms of an allergic reaction that may include skin rash, itching, difficulty in breathing or swelling of the face, lips, tongue or throat
- currently have, or in the past have had, any other medical conditions.
- have kidney disease
- have severe liver problems
- have a hereditary galactose intolerance condition (a complex carbohydrate intolerance) as Burinex® contains lactose
- have prostate gland problems
- have difficulty in passing urine
- suffer from diarrhoea or dehydration
- have diabetes or low blood pressure
- are an athlete and have to provide a urine sample
- are pregnant or breast-feeding
- are below 18 years of age
- 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

Other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Taking other medicines

Some commonly used medicines that may interfere with Burinex® include:

- Lithium, used to treat mood disorders
- Probenecid, used to treat gout
- Medicines for high blood pressure
- Digoxin, or other medicines to treat arrhythmias (heart conditions)
- Aminoglycoside antibiotics, for example gentamicin or tobramycin or other medicines which may adversely affect hearing
- Drugs that are toxic to kidneys
- NSAIDs including indomethacin, used to treat joint pain and arthritis
- Proton pump inhibitors may adversely affect magnesium levels
- Non-depolarising neuromuscular blocking agents such as suxamethonium chloride
- Any other medicines that cause low potassium blood levels

These medicines may be affected by Burinex® or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using Burinex®.

How to use Burinex®

The usual dose of Burinex® is one tablet (1mg) every day, either in the morning or early evening.

However, your doctor may recommend a different dose for you. Follow your doctor's instructions or the instructions printed on the pharmacist's label.

If you forget to take it

If you forget to take a dose, take it as soon as you remember. If your next dose is due in less than four hours, or it is near your bedtime, wait and take the next dose at the usual time.

If you have any questions, ask your doctor or pharmacist

If you use too much or use it other than directed (Overdose)

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much or use it other than directed (Overdose) immediately telephone your doctor or the Poisons Information Centre (Telephone 0800 764 766 in New Zealand) for advice or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much of Burinex®. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Burinex® you may pass too much urine, have a dry mouth, feel thirsty, weak, tired, dizzy and confused. You may also have loss of appetite, cramps and vomiting.

The treatment is to replace water and salts that have passed into the urine.

While you are using Burinex®

Things to be careful of

Be careful driving or operating machinery until you know how Burinex® affects you.

If dizziness or light-headedness occurs, do not drive a car, operate machinery, or do anything else that could be dangerous if you are not alert.

Side effects

As with all medicines, Burinex® can cause some side effects. Side effects not listed below may also occur in some patients. Ask your doctor or pharmacist to answer any questions that you may have.

Tell your doctor if you have any unpleasant effects while you are taking Burinex®, even if you do not think the effect is connected with the medicine or is not listed below.

Tell your doctor or pharmacist if you notice the following most common side effects:

- muscle cramps
- headache
- dizziness
- nausea (feeling sick)
- electrolyte imbalance
- fatigue
- feeling light-headed when you stand up quickly

Other side effects of Burinex® can include:

- impaired hearing or earache
- rash, sometimes itchy
- weakness
- pains in the stomach, joints or muscles
- vomiting
- diarrhoea

These are less common side effects of Burinex®

Tell your doctor immediately if you notice any of the following:

- fever
- chills
- sore throat
- sweats
- unexplained bruising

- an increase in breast size
- you feel unwell

These can be serious side effects. You may need urgent medical attention.

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].

This is not a complete list of all side effects.

Tell your doctor or pharmacist if you have any additional unpleasant effects while you are using Burinex®.

After using Burinex®

Storage

Keep your tablets in the blister pack until it is time to take them.

Store the blister pack in the carton to protect the tablets from light.

Keep it in a cool dry place where the temperature stays below 25 °C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Store Burinex® where children cannot reach it.

A locked cupboard at least one and-a-half meters above the ground is a good place to store medicines

Disposal

Ask your doctor or pharmacist what to do with Burinex® tablets that are left over if:

- your doctor tells you to stop using Burinex® or
- the expiry has passed

Product description

What Burinex® looks like

Burinex® are white round flat tablets, scored and imprinted on one side with the number “133”. They are individually packed in blister foils, 10 per tray. Each carton contains 10 trays, totalling 100 tablets.

Ingredients

Each Burinex® tablet contains bumetanide 1 mg as the active ingredient.

It also contains:

- starch
- lactose
- colloidal silica
- vinyl acetate copolymer
- polysorbate 80 (E433)
- agar (E406)
- magnesium stearate (E572)
- purified talc (E553(b))

This is not all the information available on Burinex®. If you have any more questions or are unsure about anything,

ask your doctor or pharmacist.

It does not contain gluten, tartrazine or any other azo dye.

Distributor

In New Zealand

AFT Pharmaceuticals Ltd
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