BURINEX®

(bue-rin-ex)

Bumetanide 1 mg tablets

Consumer Medicine Information

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. Keep this leaflet.

You may need to read it again.

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.

This medicine is available only with a doctor's prescription.

There is no evidence that Burinex® is addictive.

Before you take Burinex®

When you must not take it

Do not take Burinex® if you:

- are unable to produce urine
- are dehydrated or have been told you have very low levels of electrolytes such as potassium, sodium or chloride in your blood
- have severe liver disease which is causing a decline in your brain function including coma
- have ever had an allergic reaction to Burinex® (bumetanide) or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath or swelling of the face, lips or tongue.

Do not use after the expiry date (EXP) printed on the pack.

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

Do not take Burinex® if the packaging is torn or shows signs of tampering.

Do not give Burinex® to a child or adolescent.

Safety and use in children or adolescents under 18 years old has not been established.

Before you start to take it

You must 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
 - sulphonamide medicines (e.g. antibiotics, some medicines for

- diabetes). If you are unsure ask your doctor..
- 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
- have any type of liver disease or impairment
- · have kidney problems
- · have low blood pressure
- have been told you have abnormal levels of electrolytes in your blood
- have been feeling weak, dizzy, tired or confused
- · have difficulty in passing urine
- · have prostate gland problems
- suffer from diarrhoea, vomiting or dehydration
- · have diabetes
- · are lactose intolerant
- · are on a low salt diet
- compete in sport at a level subject to anti-doping regulations
- are pregnant, intending to become pregnant or breast-feeding.

Taking other medicines

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

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

- · lithium, used to treat mood disorders
- · probenecid, used to treat gout
- · medicines for high or low blood pressure
- medicines used to treat gastrointestinal conditions including ulcers
- medicines for heart conditions including digoxin and other medicines that are used to treat abnormal heart rhythms
- aminoglycoside antibiotics, for example Gentamicin or Tobramycin or other medicines which may adversely affect hearing
- drugs that are toxic to the kidneys
- non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or diclofenac, which are used to treat pain and arthritis
- medicines that affect the amount of potassium in your blood.

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 will advise you.

Your doctor or pharmacist has more information on medicines to be careful with, or avoid, whilst taking Burinex®.

How to take Burinex®

How much to take

The usual dose of Burinex® is one tablet (1 mg) 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.

How to take it

Burinex® tablets should be swallowed with a glass of water.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you are unsure how long to take it ask your doctor or pharmacist.

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 take too much (overdose)

If you think that you or anyone else may have taken too much Burinex®:

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital

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 feel thirsty, weak, tired, dizzy and/or confused. You may also have a dry mouth, loose your appetite, experience cramps and/or vomiting.

While you are taking Burinex®

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Burinex®.

Tell your doctor immediately if you become pregnant while you are taking Burinex®.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Burinex®, or change the dose, unless your doctor has told you to.

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.

Burinex® is banned for use in sport.

It can be detected by routine urine testing and will result in athlete disqualification.

Side effects

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well or have any unpleasant effects while you are taking Burinex®.

Tell your doctor even if you do not think the effect is because of the medicine or is not listed in this leaflet.

Ask your doctor or pharmacist to answer any questions that you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- · dizziness
- · fatigue / weakness
- · cough
- feeling light-headed when you stand up quickly.

These are mild side effects of Burinex® and are usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- · muscle weakness, pain or cramps
- · passing less urine than is normal for you
- · difficulty passing urine
- abdominal pain or discomfort nausea (feeling sick)
- · an increase in breast size in men
- blood disorders e.g. low blood cell or platelet count
- gout painful swollen joint(s)
- constipation
- dry mouth and thirst
- · an unusual amount of salts in the body
- · swelling of hands, ankles or feet

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- · impaired hearing or ear discomfort
- · rash, sometimes itchy
- vomiting
- diarrhoea
- · shortness of breath
- unexplained bruising
- · chest pain
- abnormal or irregular heartbeat.

These may be serious side effects of Burinex®. You may need urgent medical attention.

If any of the following happen, stop taking Burinex® and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

 swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

After taking it

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 this medicine in a cool dry place where the temperature stays below 25°C.

Do not store Burinex®, 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

Keep it where young children cannot reach it.

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

Disposal

If your doctor tells you to stop taking Burinex®, or the tablets have passed their expiry date, ask your pharmacist what to do with the left over tablets.

Return any unused or expired medicine to your pharmacist.

Product description

What Burinex® looks like

Burinex® tablets are white, round tablets, with a diameter of 8 mm. One side is marked with a score line and the number 133. The other side is marked with the image of a lion.

The tablets are supplied in a blister pack. Each blister tray contains 10 tablets. Each carton contains 10 blister trays and a total of 100 tablets.

Ingredients

Active ingredients:

• 1 mg bumetanide per tablet

Inactive ingredients:

- · Starch (maize)
- lactose
- silica (colloidal anhydrous)
- povidone
- polysorbate 80
- agar
- · magnesium stearate
- purified talc

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

Ask your doctor or pharmacist if you are unsure about anything or want more information about Burinex®.

Supplier

LEO Pharma Pty Ltd Level 3, Tower 1, 25 Montpelier Road Bowen Hills, QLD 4006 AUSTRALIA

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