

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using BURINEX?

BURINEX contains the active ingredient bumetanide. BURINEX is used 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.

For more information, see Section [1. Why am I using BURINEX?](#) in the full CMI.

### 2. What should I know before I use BURINEX?

Do not use if you have ever had an allergic reaction to BURINEX or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BURINEX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BURINEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use BURINEX?

- Use BURINEX only when prescribed by your doctor. Follow the instructions provided and use BURINEX until your doctor tells you to stop.
- The usual dose of BURINEX is one tablet (1 mg) every day; however, your doctor may recommend a different dose for you.

More instructions can be found in Section [4. How do I use BURINEX?](#) in the full CMI.

### 5. What should I know while using BURINEX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BURINEX.</li><li>• If you become pregnant while using BURINEX, inform your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or change the dose, unless your doctor has told you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how BURINEX affects you.</li><li>• BURINEX may cause dizziness in some people, which may affect your ability to drive and use machines.</li></ul>
<b>Participating in sports</b>	<ul style="list-style-type: none"><li>• BURINEX is banned for use in sport at a <b>level subject to anti-doping regulations</b>.</li><li>• It can be detected by routine urine testing and will result in athlete disqualification.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25 °C. Keep the blister in the carton to protect it from light.</li></ul>

For more information, see Section [5. What should I know while using BURINEX?](#) in the full CMI.

### 6. Are there any side effects?

**SERIOUS SIDE EFFECTS:** related to [allergic reaction](#) (sudden onset of swelling of face/lips/tongue causing difficulty to breathe, [itchy] rash, shortness of breath), [heart](#) (chest pain, abdominal/irregular heartbeat), [gastrointestinal](#) (vomiting, diarrhoea), [other](#) (impaired hearing/ear discomfort, unexplained bruising).

**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

**COMMON SIDE EFFECTS:** related to [alertness & orientation](#) (headache, dizziness, fatigue, weakness, light-headedness when standing up quickly), [respiratory](#) (cough), [kidney](#) (passing less urine/difficulty passing urine, dry mouth/thirst), [pain](#) (muscle weakness/pain/cramps, gout – painful swollen joint[s]), [circulation](#) (swollen hands/ankles/feet), [gastrointestinal](#) (tummy ache/discomfort, nausea, constipation), [other](#) (increased breast size [men], blood disorders [low blood cell/platelet count], unusual amount of salts in the body).

**Speak to your doctor if you have any of these less serious side effects and they worry you.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Active ingredient: *bumetanide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using BURINEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BURINEX.**

Where to find information in this leaflet:

- [1. Why am I using BURINEX?](#)
- [2. What should I know before I use BURINEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BURINEX?](#)
- [5. What should I know while using BURINEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using BURINEX?

**BURINEX contains the active ingredient bumetanide.** BURINEX belongs to a group of medicines called diuretics. Diuretics are medicines that make the kidneys produce more urine.

**BURINEX is effective treatment 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.**

### 2. What should I know before I use BURINEX?

#### Warnings

**Do not use BURINEX if:**

- You are allergic to bumetanide, or any of the ingredients listed at the end of this leaflet
- Always check the ingredients to make sure you can use this medicine
- Your body is unable to produce urine
- You suffer from a severe liver disease which causes a decline in brain function, including coma
- You suffer from a shortage of salts or chemicals in the blood
- Symptoms of an allergic reaction may include skin rash, itching, hives, shortness of breath, or swelling of the face, lips or tongue.

**Check with your doctor if you:**

- have any other medical conditions such as:
  - an imbalance of salts or chemicals in the blood
  - an imbalance of blood volume
  - low blood pressure

- lactose intolerance (cannot fully digest the sugar [lactose] in milk after eating or drinking dairy products)
- diabetes (high blood sugar)
- kidney problems
- prostate gland problems
- difficulty to urinate
- liver problems, including liver damage
- a build-up of fluid in your belly
- allergies to any other medicines, foods, preservatives or dyes
- Compete in sport at a level subject to anti-doping regulations
- Take any medicines for any other condition
- Have been feeling weak, dizzy, tired or confused
- Suffer from diarrhoea, vomiting or dehydration
- Are on a low salt diet.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not use BURINEX if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits of using BURINEX during breastfeeding and a decision can be made if you should or should not use it.

#### Allergy to sulphonamides

People who are allergic to sulphonamides may also show allergic reactions when taking BURINEX. Sulphonamides are a type of antibiotic used to treat certain bacterial infections.

Check with your doctor or pharmacist if you are not sure whether you are allergic to sulphonamides.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 used to treat high or low blood pressure
- Medicines used to treat heart conditions, including digoxin

- Medicines which can affect the hearing negatively, e.g. aminoglycoside antibiotics (like gentamicin and tobramycin)
- Medicines that are toxic to the kidneys
- Non-steroidal anti-inflammatory drugs (NSAIDs), e.g. ibuprofen and diclofenac (used to treat pain and arthritis)
- Medicines that affect the amount of potassium in your blood
- Medicines used to treat abnormal heart rhythms
- Medicines used to treat gastrointestinal conditions, including ulcers.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BURINEX.**

## 4. How do I use BURINEX?

### How much to take

- The usual dose of BURINEX is one tablet (1 mg) every day; however, your doctor may recommend a different dose for you
- Follow the instructions provided and use BURINEX until your doctor tells you to stop.

### When to take BURINEX

- BURINEX should be used either in the morning or early evening.

### How to take BURINEX

- 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.

### If you forget to use BURINEX

BURINEX should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

**If your next dose is due in less than 4 hours, or it is near your bedtime, wait and take the next dose at the usual time.**

**Do not take a double dose to make up for the dose you missed.**

If you have any questions, ask your doctor or pharmacist.

### If you use too much BURINEX

If you think that you have used too much BURINEX, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

If you take too much BURINEX you may feel thirsty, weak, tired, dizzy and/or confused. You may also have a dry mouth, loss of appetite, experience cramps and/or vomiting.

## 5. What should I know while using BURINEX?

### Things you should do

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

#### Call your doctor straight away if you:

- Become pregnant while you are taking BURINEX.

Remind any doctor, dentist or pharmacist you visit that you are using BURINEX.

### Things you should not do

- Do not stop using this medicine or change the dose, unless your doctor has told you to
- 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.

### Competing in sports

- BURINEX is banned for use in sport at a level subject to anti-doping regulations
- It can be detected by routine urine testing and will result in athlete disqualification.

BURINEX is not addictive.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how BURINEX affects you.**

BURINEX may cause dizziness in some people, which may affect your ability to drive and use machines.

### Drinking alcohol

Alcohol is not expected to have any effect on the use of BURINEX.

### Looking after your medicine

- Store below 25 °C. Keep the blister in the carton to protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

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 remaining tablets.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Alertness- and orientation-related:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• Dizziness</li><li>• Fatigue</li><li>• Weakness</li><li>• Feeling light-headed when you stand up quickly</li></ul> <b>Respiratory-related:</b> <ul style="list-style-type: none"><li>• Cough</li></ul> <b>Kidney-related:</b> <ul style="list-style-type: none"><li>• Passing less urine than what is normal for you</li><li>• Difficulty passing urine</li><li>• Dry mouth and thirst</li></ul> <b>Pain-related:</b> <ul style="list-style-type: none"><li>• Muscle weakness, pain or cramps</li><li>• Gout – painful swollen joint(s)</li></ul> <b>Circulation-related:</b> <ul style="list-style-type: none"><li>• Swelling of hands, ankles or feet</li></ul> <b>Gastrointestinal-related:</b> <ul style="list-style-type: none"><li>• Tummy ache or discomfort</li><li>• Nausea (feeling sick)</li><li>• Constipation</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>• Increased breast size in men</li><li>• Blood disorders e.g. low blood cell or platelet count</li><li>• An unusual amount of salts in the body</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Allergic reaction:</b> <u>Sudden onset of:</u> <ul style="list-style-type: none"><li>• Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing</li><li>• Rash, sometimes itchy</li><li>• Shortness of breath</li></ul> <b>Heart-related:</b> <ul style="list-style-type: none"><li>• Chest pain</li><li>• Abnormal or irregular heartbeat</li></ul> <b>Gastrointestinal-related:</b> <ul style="list-style-type: none"><li>• Vomiting</li><li>• Diarrhoea</li></ul> <b>Other:</b> <ul style="list-style-type: none"><li>• Impaired hearing or ear discomfort</li><li>• Unexplained bruising</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What BURINEX contains

<b>Active ingredient (main ingredient)</b>	Bumetanide
<b>Other ingredients (inactive ingredients)</b>	Maize starch Lactose Colloidal anhydrous silica Povidone Polysorbate 80 Agar Magnesium stearate Purified talc

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What BURINEX looks like**

BURINEX® tablets are white, flat and round (with a diameter of 8 mm). One side is marked with a score line and the number 133.

BURINEX® tablets are supplied in PVC/aluminium blisters and are packed in cartons containing 100 tablets.

(AUST R 51734)

## **Who distributes BURINEX**

AFT Pharmaceuticals Pty Ltd

113 Wicks Road

North Ryde

NSW 2113

Email: [customer.service@aftp pharm.com](mailto:customer.service@aftp pharm.com)

Freephone (AU): 1800 AFTPHARM (1800 238 74276)

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