

# APO-Frusemide Tablets

Contains the active ingredient furosemide (frusemide)

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## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

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### What is in this leaflet

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#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about furosemide (frusemide). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

#### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

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### What this medicine is used for

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The name of your medicine is APO-Frusemide. It contains the active ingredient furosemide (frusemide).

Furosemide (frusemide) is used to treat swelling of the ankles, feet, legs or even the brain or lungs. This swelling is called oedema and can occur in some heart, lung, liver or kidney conditions.

Furosemide (frusemide) may be used in some patients with more serious kidney problems who may have some fluid retention.

Furosemide (frusemide) may also be used to lower high blood pressure (which is also called hypertension).

Everyone has blood pressure. This pressure helps move your blood around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Furosemide (frusemide) may be taken alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed furosemide (frusemide) for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

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

#### How it works

Furosemide (frusemide) belongs to a family of drugs called diuretics. A diuretic helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

This medicine is not addictive.

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### Before you take this medicine

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#### When you must not take it

#### Do not take this medicine if:

- **You have or have had any of the following:**
  - **certain kidney problems**
  - **no production or no passing of urine**
  - **low blood pressure (hypotension)**
  - **low sodium levels in your blood**
  - **low potassium levels in your blood**
  - **dehydration.**

- **You are pregnant.**  
Furosemide (frusemide) may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.**  
Furosemide (frusemide) may pass into human breast milk.
- **You are hypersensitive to, or have had an allergic reaction to, furosemide (frusemide), sulfonamides or any of the ingredients listed at the end of this leaflet.**  
Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.  
**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

### *Before you start to take it*

#### **Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
    - any other medicines
    - any other substances, such as foods, preservatives or dyes.
  2. You have or have had any medical conditions, especially the following:
    - liver problems
    - kidney problems
    - heart problems
    - high cholesterol levels
    - asthma
    - diabetes
    - gout, a disease with painful, swollen joints
- passing less urine than is normal for you
  - difficulty passing urine
  - prostate problems
  - Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
  4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
  5. You are planning to have surgery or an anaesthetic.
  6. You are currently receiving or are planning to receive dental treatment.
  7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.
- Tell your doctor if you are on a salt restricted diet.
- If you have not told your doctor about any of the above, tell them before you take furosemide (frusemide).**
- Some medicines may interfere with furosemide (frusemide). These include:
- certain other fluid tablets or diuretic medicines such as ethacrynic acid
  - medicines used to treat high blood pressure and some other heart conditions, especially ACE inhibitors or angiotensin receptor antagonists
  - digoxin and other medicines used to treat heart failure
  - non-steroidal anti-inflammatory drugs (NSAIDs) and aspirin, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
  - medicines used to relax muscles such as tubocurarine and succinylcholine
  - lithium, a medicine used to treat mood swings and some types of depression
  - medicines used in emergency situations such as adrenaline and noradrenaline
  - cisplatin, a medicine used to treat cancer
  - theophylline, a medicine used to treat asthma
  - certain antibiotics, especially cephalosporins and aminoglycosides
  - amphotericin, a medicine used to treat fungal infections
  - barbiturates, medicine used to treat epilepsy, to produce calmness, or to help you sleep
  - narcotic/strong pain killers such as codeine and morphine
  - medicines used to treat diabetes such as insulin
  - sucralfate, a medicine used to treat stomach ulcers
  - anticonvulsant medicines such as chloral hydrate or phenytoin
  - corticosteroids such as cortisone, prednisone or dexamethasone
  - medicines used during scans to see the images of your body
  - methotrexate and cyclosporine A, medicines that suppress the immune
  - carbenoxolone, used to treat ulcers of the mouth or oesophagus
  - medicines used to treat thyroid conditions
  - risperidone, used to treat a number of mood disorders
  - large amounts of laxatives (medicines for constipation).
- These medicines may be affected by furosemide (frusemide), or may affect how well it works. If you are taking any of these you may need a different dose or you may need to take different medicines. Your doctor will advise you.
- You should not eat large amounts of liquorice when you are taking furosemide (frusemide).

Other medicines not listed above may also interact with furosemide (frusemide).

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## How to take this medicine

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Follow the directions given to you by your doctor carefully.

Their instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

### **Oedema**

Adults: 20 to 80 mg as a single dose. The dose may be increased in exceptional cases up to 400 mg per day.

Children: 2 mg per kg bodyweight per day. The dose may be increased by 1-2mg per kg and should not exceed 6mg per kg bodyweight.

### **Hypertension**

Adults: The recommended dosage is 40 mg twice daily. The dose may be adjusted according to the patient's response.

### *How to take it*

Swallow furosemide (frusemide) tablets with a glass of water.

### *When to take it*

Furosemide (frusemide) tablets are usually taken once or twice a day.

Take furosemide (frusemide) tablets on an empty stomach. For example, one hour before food or two hours after food. Food can interfere with the absorption of furosemide (frusemide) tablets.

Take furosemide (frusemide) tablets at about the same time each day

unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

If you are taking a single dose a day, take it in the morning, for example before breakfast. If you are taking more than one dose a day, take the last dose no later than 2 pm, unless your doctor tells you otherwise.

Furosemide (frusemide) may increase the amount of urine you pass; it will also increase the number of times you need to go to the toilet. By taking your last dose around 2 pm, there may be less chance that your sleep is disturbed.

### *How long to take it for*

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

Ask your doctor if you are not sure how long to take the medicine for.

### *If you forget to take it*

This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

### **Do not take a double dose to make up for missed doses.**

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

If you have trouble remembering when to take your medicine, ask your pharmacist for hints to help you remember.

### *If you take too much (overdose)*

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

**you or anyone else may have taken too much furosemide (frusemide).**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

If you take too much furosemide (frusemide), you may feel confused, dehydrated, dizzy or you may pass excessive urine.

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

### *Things you must not do*

#### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

### *Things to be careful of*

**Make sure you drink enough water during any exercise and during hot**

**weather when you are taking furosemide (frusemide), especially if you sweat a lot.**

If you do not drink enough water while taking furosemide (frusemide), you may feel faint or light-headed or sick. This is because your blood pressure is dropping suddenly and you are dehydrating. If you continue to feel unwell, tell your doctor.

**If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.**

You may feel light-headed or dizzy when you begin to take furosemide (frusemide). This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from beds or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

**Be careful driving or operating machinery until you know how furosemide (frusemide) affects you.**

Diuretic medicines may cause dizziness or light-headedness in some people. Make sure you know how you react to your medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded.

**If this occurs do not drive.**

If you drink alcohol or take strong painkillers, dizziness or light-headedness may be worse.

**The effects of alcohol could be made worse while taking furosemide (frusemide). It is not recommended that you drink alcohol while taking furosemide (frusemide).**

If you are taking furosemide (frusemide) for a long period of time, you should check with your doctor to determine whether or not you should eat more potassium-containing foods or take potassium supplements.

However, increasing the amount of potassium in your diet may not be necessary and could be harmful. Check with your doctor.

Furosemide (frusemide) may cause your skin to become more sensitive

to the sun. If this happens you should take care to wear protective clothing including a hat and sun block when you are outside.

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## Possible side effects

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Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following list of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious, but most of the time they are not.

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

- very dry mouth or unusual thirst
- weight loss
- weakness or tiredness
- numbness or tingling in the hands and/or feet
- calf muscle spasms
- muscle pains or cramps
- joint pain or stiffness
- restlessness
- drowsiness or a lack of energy
- dizziness or light-headedness
- headache
- fever
- vomiting or nausea
- diarrhoea
- blurred or impaired vision
- unusual bleeding or bruising under the skin
- ringing or buzzing in the ears
- confusion.

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

These may be serious side effects of furosemide (frusemide) and you may need urgent medical attention.

- irregular or fast heart beat
- passing less urine than is normal for you
- severe stomach pain, often with nausea or vomiting

- severe dizziness or a spinning sensation
- increased sensitivity to sunlight
- flaking or peeling of the skin
- symptoms of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds
- loss of control of your bladder or bowels (incontinence)
- gout, a disease with painful, swollen joints
- deafness or ringing in the ears.

**If you experience any of the following stop taking your medicine and contact your doctor or immediately go to the Accident and Emergency at your nearest hospital:**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- chest pain
- fainting or having a rapid, weak pulse
- lockjaw
- red, often itchy spots similar to the rash seen with measles which starts on the limbs and sometimes on the face and body. The spots may blister and may progress to form raised red, pale-centred marks. Those affected may have fever, sore throat, headache with or without diarrhoea.
- yellowing of the skin and/or eyes (jaundice).

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

### *Allergic reactions*

**If you think you are having an allergic reaction to furosemide (frusemide), do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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### *Storage*

Keep your furosemide (frusemide) tablets in the bottle until it is time to take them.

If you store your furosemide (frusemide) tablets out of the container they may not keep well.

Keep your furosemide (frusemide) tablets in a cool dry place where the temperature stays below 25°C.

Do not store furosemide (frusemide) tablets or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat, sunlight and dampness can destroy some medicines.

Keep it where 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 furosemide (frusemide) or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over. Return any unused medicine to your pharmacist.

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## Product description

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### *What APO-Frusemide looks like*

#### **20 mg tablets:**

White to off-white round tablets, debossed with 'F2' on one side and plain on the other side.

Packaged in bottles of 50 and 100 tablets.

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Packaged in bottles of 50 and 100 tablets.

#### **40 mg tablets:**

White to off-white round tablets, debossed with 'F4' on one side and breakline on the other side.

Packaged in bottles of 30, 50, 60 and 100 tablets.

\* Not all strengths and/or pack sizes may be available.

### *Ingredients*

Each tablet contains 20 mg or 40 mg of furosemide (frusemide) as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- maize starch
- pregelatinised maize starch,
- sodium starch glycollate (type A)
- magnesium stearate.

This medicine is gluten-free and free of azo dyes.

### *Australian Registration Numbers*

APO-Frusemide 20 mg tablets:  
AUST R 186517.

APO-Frusemide 40 mg tablets:  
AUST R 186516.

### *Sponsor*

Apotex Pty Ltd  
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This leaflet was last updated in:  
February 2018