

## 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 MONOPRIL?

MONOPRIL contains the active ingredient fosinopril sodium. MONOPRIL is used to treat high blood pressure (hypertension) or heart failure.

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

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

Do not use if you have ever had an allergic reaction to fosinopril sodium or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions or allergies, 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 MONOPRIL?](#) in the full CMI.

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

Some medicines may interfere with MONOPRIL 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 MONOPRIL?

- MONOPRIL is usually taken at a dose of 10mg to 40mg once a day. Your doctor will tell you how much to take each day.
- MONOPRIL is taken once a day at about the same time each day.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist, anesthetists, you visit that you are using MONOPRIL.</li><li>• Make sure you drink enough water during exercise and hot weather.</li><li>• If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine or lower the dosage without checking with your doctor.</li><li>• Do not take MONOPRIL if you are pregnant or plan to become pregnant or breastfeed</li><li>• Do not take a double dose to make up for the dose that you missed</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 MONOPRIL affects you.</li><li>• MONOPRIL may cause dizziness, or light-headedness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• If you drink alcohol, dizziness or light-headedness may be worse.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the blister pack until it is time to take them.</li><li>• Keep MONOPRIL tablets in a cool dry place, in the dark, where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

More common side effects include: feeling lightheaded, dizzy or faint; headache; tiredness, fatigue or weakness; dry cough; muscle cramps or pain; nausea or vomiting; upset stomach; stomach pain; heartburn; diarrhoea.

Serious Side effects include: Swollen face, swollen lips, swollen mouth, swollen throat, swollen hands or feet; fainting; yellowing skin; not urinating as much as usual; sore throat and fever; stomach pain; chest pain; difficulty breathing; itchy skin and/or rash; changes to your heart rhythm, inability to get or maintain an erection; severe dizziness; gout; diabetes; infections in your urinary tract or upper respiratory tract; hepatitis; confusion; nervousness; numbness or tingling of the hands feet or lips; shortness or breath; weakness or heaviness of legs.

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.

# MONOPRIL<sup>®</sup> (MON-o-pril)

Active ingredient(s): *Fosinopril Sodium* (FOS-in-O-pril SOH-dee-uhm)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MONOPRIL. **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 MONOPRIL.**

Where to find information in this leaflet:

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

## 1. Why am I using MONOPRIL?

MONOPRIL contains the active ingredient **fosinopril sodium**.

MONOPRIL is used for treating **high blood pressure (hypertension) or heart failure**. Both of these are long term (chronic) diseases so it is important that you continue to take your MONOPRIL every day.

Fosinopril sodium belongs to a class of medicines known as ACE inhibitors. It works by widening your blood vessels, reducing the pressure in the vessels (reducing 'blood pressure') and by making it easier for your heart to pump blood around your body. This helps your heart to work better by increasing the supply of oxygen to your heart.

### High blood pressure (hypertension):

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

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

### Heart Failure:

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops. Heart failure may start off with no symptoms, but as the condition progresses, patients feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Your doctor may have prescribed MONOPRIL for another reason.

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

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

### Warnings

#### Do not use MONOPRIL if:

- you are allergic to fosinopril sodium (the active ingredient in MONOPRIL), or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to MONOPRIL may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

Always check the ingredients to make sure you can use this medicine.

- you have taken any other 'ACE inhibitor' medicine before, which caused your face, lips, tongue, throat, hands or feet to swell up or made it hard for you to breathe.

If you have had an allergic reaction to an ACE inhibitor medicine before, you may be allergic to MONOPRIL.

- you have a history of angioedema or angioneurotic oedema, which is swelling of the face, lips, tongue, throat (which may cause difficulty in swallowing or breathing), hands or feet, for no apparent reason.

#### Check with your doctor if you:

- have allergies to:
  - any other medicine
  - any other substances, such as foods, preservatives or dyes
- you have a family history of swelling of the face, lips, tongue, throat that may cause difficulty in swallowing or breathing.
- have any medical conditions, especially the following:
  - diabetes
  - take any other medicines or drugs including any immunosuppressant medicine or trimethoprim containing medicines
  - kidney problems, or have had kidney problems in the past, or are having dialysis
  - liver problems, or have had liver problems in the past
  - low blood pressure, which you may notice as dizziness or lightheadedness
  - are going to have surgery (including dental surgery) involving a general anaesthetic, even if it is minor

- are pregnancy or plan to become pregnant or breastfeed.

**If you have not told your doctor about any of the above, tell them before you start taking MONOPRIL.**

If you are not sure whether you should start taking MONOPRIL, talk to your doctor.

MONOPRIL is not addictive.

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**

**Do not take MONOPRIL if you are pregnant or are trying to become pregnant.**

MONOPRIL may cause serious injury to your developing baby if you take it during pregnancy.

**Do not take MONOPRIL if you are breastfeeding or intend to breastfeed.**

### **Children**

The safety and effectiveness of MONOPRIL in children has not been established.

## **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 medicines can affect the way MONOPRIL works. It is especially important that you tell your doctor if you are taking any of the following:

- water tablets or diuretics
- lithium or lithium-containing preparations
- potassium tablets
- potassium-containing salt substitutes
- antacids
- if you are taking MONOPRIL for high blood pressure do not take any medicine (including ones bought without prescription) for appetite control, asthma, colds, coughs, hayfever or sinus problems unless you have discussed the medicine with your doctor or pharmacist.
- aspirin
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents - NSAIDs and COX-2 inhibitors. Taking a combination of Monopril with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.
- medicines that lower your immune system, such as medicines used to prevent rejection of transplant organs.
- trimethoprim containing medicines used to treat certain types of infections

Your doctor will decide whether your treatment needs to be altered or whether you should have check ups or blood tests more frequently

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

## **4. How do I use MONOPRIL?**

### **How much to take**

- MONOPRIL is usually taken at a dose of 10mg to 40mg once a day. Your doctor may have prescribed a different dose for you.
- Your doctor or pharmacist will tell you how many tablets you will need to take each day.
- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information in this leaflet.

### **When to take MONOPRIL**

- Take MONOPRIL at about the same time each day.  
Taking your tablet at about the same time each day will help you to remember when to take it.
- MONOPRIL helps to control your condition but does not cure it. Therefore you must take MONOPRIL every day. Continue taking it for as long as your doctor tells you.

### **How to take MONOPRIL**

- It does not matter if you take MONOPRIL before or after food.
- If you need to take an antacid, take it at least 2 hours before or two hours after your dose of MONOPRIL.
- If you do not understand the instructions on the label on the box, ask your doctor or pharmacist for help.

### **If you forget to use MONOPRIL**

MONOPRIL should be used regularly at the same time each day.

**If you forget to take one or more doses of MONOPRIL, if it is almost time for your next dose, skip the dose you missed and take your next dose at the normal time and in the normal amount.**

**Otherwise 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 the dose that you missed. Do not take any more than your doctor prescribed for you.**

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### **If you use too much MONOPRIL**

If you think that you have used too much MONOPRIL, 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.**

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

### Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking MONOPRIL.
- If you are about to be started on a new medicine, tell your doctor, dentist or pharmacist that you are taking MONOPRIL.
- **Make sure you drink enough water during exercise and hot weather when you are taking MONOPRIL, especially if you sweat a lot.**

If you do not drink enough water while taking MONOPRIL, your blood pressure may drop suddenly and you may dehydrate. If you experience any of the above symptoms, tell your doctor.

- **If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking MONOPRIL.**

Having a general anaesthetic while taking MONOPRIL may also cause your blood pressure to drop suddenly.

- **If you are about to have blood tests, tell your doctor that you are taking MONOPRIL.**

MONOPRIL may interfere with the results of some tests.

- **Have your blood pressure checked when your doctor says, to make sure MONOPRIL is working.**
- **Go to your doctor regularly for a check-up.**

Your doctor may like to do blood tests to see how MONOPRIL is affecting you.

- As with other ACE inhibitor medicines, you may feel light-headed or dizzy when you begin to take MONOPRIL or after your dose is increased. This is because your blood pressure is dropping suddenly.

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

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. Be careful the first time you take MONOPRIL, especially if you are elderly.

### Call your doctor straight away if you:

- Have excessive vomiting or diarrhoea
- Experience any of the following symptoms:
  - light-headed or dizzy
  - dry mouth or thirst

- weakness, tiredness or drowsiness
- muscle pain or cramps
- fast heart beat
- passing less urine than normal

If you experience these symptoms, you may be dehydrated because you are losing too much water.

This is more likely to occur when you begin to take MONOPRIL or if your dose is increased.

- Become pregnant while taking MONOPRIL

### Things you should not do

- Do not give MONOPRIL to anyone else, even if they have the same condition as you.
- Do not take MONOPRIL to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking MONOPRIL, or lower the dosage, without checking with your doctor.
- Do not take MONOPRIL after the expiry date printed on the pack.
- Do not take MONOPRIL if the packaging is torn or shows signs of tampering.
- Do not take MONOPRIL if the tablets change in appearance, colour or taste.

### Things that would be helpful for your blood pressure

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol**

Your doctor may advise you to limit your alcohol intake.

- **Weight**

Your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

- **Diet**

Eat a healthy low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.

- **Salt**

Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.

- **Exercise**

Regular exercise helps to reduce blood pressure and helps to get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. Before starting any exercise, ask your doctor about the best kind of programme for you.

- **Smoking**

Your doctor may advise you to stop smoking or at least cut down.

## Driving or using machines

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

As with other ACE inhibitor medicines, MONOPRIL may cause dizziness, or light-headedness in some people. Make sure you know how you react to MONOPRIL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

## Looking after your medicine

- Keep your tablets in the blister pack until it is time to take them.  
If you take the tablets out of the pack they will not keep well.
- Keep MONOPRIL tablets in a cool dry place, in the dark, where the temperature stays below 25°C.

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.

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.

## When to discard your medicine

If it has expired or is damaged return it to your pharmacist for disposal.

## 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.

## 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.

### Serious side effects

Serious side effects	What to do
Swelling	Call your doctor straight away, or go straight to the

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Swollen face, swollen lips, swollen mouth, swollen throat, swollen hands or feet</li> </ul> <p><b>Liver and Kidneys</b></p> <ul style="list-style-type: none"> <li>if you faint or if your skin turns yellow</li> <li>not urinating (passing water) as much as usual</li> </ul> <p><b>Infection</b></p> <ul style="list-style-type: none"> <li>sore throat and fever</li> </ul> <p><b>Stomach</b></p> <ul style="list-style-type: none"> <li>stomach pain with or without nausea</li> </ul> <p><b>Heart and Lungs:</b></p> <ul style="list-style-type: none"> <li>chest pain</li> <li>difficulty breathing</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>itchy skin and/or rash</li> </ul>	<p><b>Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
Rare serious side effects	What to do
<p><b>Heart</b></p> <ul style="list-style-type: none"> <li>changes to your heart rhythm</li> </ul> <p><b>Genitals</b></p> <ul style="list-style-type: none"> <li>impotence (inability to get or maintain an erection)</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>mild rash or itching</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>severe dizziness (vertigo)</li> <li>gout (painful, swollen joints)</li> <li>diabetes (symptoms include - excessive thirst, greatly increased amount of urine, increase of appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell)</li> </ul> <p><b>Infection</b></p> <ul style="list-style-type: none"> <li>sore throat and fever</li> <li>infections of your urinary tract or upper respiratory tract (URTI, or cold or flu symptoms)</li> </ul> <p><b>Liver</b></p> <ul style="list-style-type: none"> <li>hepatitis (symptoms include - nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine)</li> </ul> <p><b>Potassium Build-up</b></p>	<p><b>Call your doctor as soon as possible if you notice any of these rare side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>confusion; irregular heartbeat; nervousness; numbness or tingling of the hands, feet or lips; shortness of breath or difficulty breathing; weakness or heaviness of legs. (You may experience these symptoms if too much potassium builds up in your body.)</li> </ul>	

### Other side effects

More Common side effects	What to do
<p><b>Head</b></p> <ul style="list-style-type: none"> <li>feeling lightheaded, dizzy or faint</li> <li>headache</li> </ul> <p><b>General</b></p> <ul style="list-style-type: none"> <li>tiredness, fatigue or weakness</li> <li>dry cough</li> <li>muscle cramps or pains</li> </ul> <p><b>Gut and Digestive System</b></p> <ul style="list-style-type: none"> <li>feeling sick (nausea) or vomiting</li> <li>upset stomach (dyspepsia) or heartburn</li> <li>diarrhoea</li> <li>stomach pains</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

**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 MONOPRIL contains

<b>Active ingredient (main ingredient)</b>	Fosinopril sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>Lactose</li> <li>Microcrystalline cellulose</li> <li>Crospovidone</li> <li>Povidone</li> <li>Sodium stearyl fumarate.</li> </ul>

<b>Potential allergens</b>	Contains sugars as lactose
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**Do not take this medicine if you are allergic to any of these ingredients.**

### What MONOPRIL looks like

#### MONOPRIL 10mg tablets -

White biconvex, diamond shaped tablet and marked on one side and with a star design and on the other side '158' (AUST R 46475). Each carton contains 30 tablets.

### Who distributes MONOPRIL

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: [MedInfo.Australia@bms.com](mailto:MedInfo.Australia@bms.com)

Monopril is a registered trademark of Bristol-Myers Squibb

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