

# FIBSOL

## 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 FIBSOL?

FIBSOL contains the active ingredient lisinopril (as dihydrate). FIBSOL is used to lower high blood pressure, which doctors call hypertension. It is also used to treat heart failure and patients who have just had a heart attack. For more information, see Section [1. Why am I using FIBSOL?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to lisinopril 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 FIBSOL?](#) in the full CMI.

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

Some medicines may interfere with FIBSOL 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 FIBSOL?

- Take FIBSOL as prescribed by your doctor. This depends on your condition and whether you are taking other medicines.

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

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

<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 FIBSOL.</li><li>• Have your blood pressure checked when your doctor says to make sure FIBSOL is working.</li><li>• <b>Call your doctor straight away if you:</b> feel any light-headedness or dizziness, become pregnant, have excessive vomiting and/or diarrhoea while taking FIBSOL.</li><li>• Make sure you drink enough water during exercise and hot weather when you are taking FIBSOL.</li><li>• Go to your doctor regularly for a check-up.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take FIBSOL to treat any other complaints unless your doctor tells you to.</li><li>• Do not give FIBSOL to anyone else, even if they have the same condition as you.</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 FIBSOL affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Your doctor may advise you to limit your alcohol intake.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C.</li><li>• Store in a cool, dry place, away from young children.</li></ul>

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

### 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are passing less urine, chest pain, angina, swelling of the face, lips, mouth, tongue or throat, wheeziness, difficulty breathing, collapse, numbness/weakness of arms or legs, pinkish, hives, fainting, heart beats changes, skin problems, infections, bruising easily, severe abdominal pain, yellowing of the skin and/or eyes, dehydration and hallucinations. 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.

# FIBSOL

Active ingredient: *lisinopril (as dihydrate)*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I using FIBSOL?

FIBSOL contains the active ingredient **lisinopril (as dihydrate)**.

Lisinopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

**FIBSOL is used to lower high blood pressure, which doctors call hypertension. It is also used to treat heart failure and patients who have just had a heart attack.**

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

### Warnings

**Do not use FIBSOL if:**

- you are allergic to lisinopril, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have taken any medicines called 'ACE inhibitors' before and have had allergic reactions with swelling of the hands, feet, or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing or if you or a member of your family have had a similar reaction.
  - If you or a family member has had an allergic reaction to an ACE inhibitor before, you may be allergic to FIBSOL.
- you or a member of your family has a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.
  - Some of the symptoms of an allergic reaction to FIBSOL may include skin rash, itchiness, difficulty breathing or swallowing, or swelling of the face, lips, tongue or throat.
- you are undergoing haemodialysis.

- you are taking a blood pressure medicine containing aliskiren and you have diabetes mellitus.
- you are taking a blood pressure medicine containing aliskiren and you have kidney problems.

**Check with your doctor if you:**

- have any other medical conditions, including
  - kidney problems, or are undergoing dialysis
  - low blood pressure (you may notice this as faintness or dizziness, especially when standing)
  - liver problems
  - Diabetes
  - aortic stenosis (narrowing of the aorta), renal stenosis (narrowing of the renal artery) or hypertrophic cardiomyopathy (an increase in the thickness of the heart muscle)
  - diarrhoea or vomiting
- take any medicines for any other condition
- if you are following a very low salt diet
- if you are going to receive desensitisation treatment for an allergy, e.g. to insect stings
  - The desensitisation treatment reduces the effects of the allergy (e.g. bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking an ACE inhibitor during the desensitisation treatment.
- if you are taking medicines called mTOR inhibitors (such as temsirolimus, everolimus, sirolimus) or medicines containing NEP inhibitors (such as racecadotril).
  - Taking these medicines with FIBSOL may increase the risk of angioedema. Signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

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.

FIBSOL is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

FIBSOL should not be used while breastfeeding or if planning to breastfeed.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

### 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 may interfere with FIBSOL and affect how it work, and some medicines may be affected by FIBSOL**

- medicines used to treat high blood pressure or heart problems called angiotensin II receptor blockers, such as candesartan, valsartan, telmisartan, olmesartan or irbesartan.
- other medicines used to treat high blood pressure, including any that contain aliskiren (see also information under the heading "When you must not take it").
- diuretic tablets - also called fluid or water tablets
- lithium, a medicine used to treat some types of mental disorders
- potassium tablets, salt substitutes containing potassium or other medicines which can increase potassium in your body.
- non-steroidal anti-inflammatory medicines used to treat arthritis and muscle pain, such as indomethacin, naproxen or ibuprofen.
- heparin, a medicine used to prevent blood clots.
- a medicine used to treat infection containing sulfamethoxazole and trimethoprim, also known as co-trimoxazole.
- gold injections (such as sodium aurothiomalate) usually used to treat rheumatoid arthritis.
- insulin or other medicines used to treat diabetes.
- medicines used to break down blood clots such as alteplase or reteplase.
- medicines called mTOR inhibitors (such as temsirolimus, everolimus, sirolimus) or medicines containing NEP inhibitors (such as racecadotril).

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

### 4. How do I use FIBSOL?

#### How much to take

- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.
- Take FIBSOL only when prescribed by your doctor.
- For high blood pressure:
  - For most patients, the usual starting dose is 5mg to 10mg taken once a day.
  - Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure.
  - Most patients take between 10mg to 20mg each day, taken once a day.
- For heart failure:

- The usual starting dose is 2.5 mg taken once a day.
- Depending on your response, this dose may need to be increased.
- The usual dose is between 5 mg to 20 mg each day, taken once a day.
- For heart attack:
  - FIBSOL may be started within 24 hours of the onset of the symptoms of heart attack. The usual starting dose is 5 mg, which is followed 24 hours later by another 5 mg dose.
- This is then followed 48 hours later by a 10 mg dose, and then 10 mg taken once a day thereafter. Some patients may need a lower starting and maintenance dose.

#### How long to take FIBSOL

- Continue taking the tablets for as long as your doctor tells you.
- FIBSOL helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore, you must take FIBSOL every day.
- **Do not stop taking your medicine or change your dosage without first checking with your doctor.**

#### When to take FIBSOL

- FIBSOL should be used at about the same time each day. Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

#### How to take FIBSOL

- Swallow FIBSOL with a glass of water or other liquid.
- It does not matter if you take FIBSOL before or after food.

#### If you forget to use FIBSOL

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

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

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

#### If you use too much FIBSOL

If you think that you have used too much FIBSOL, you may need urgent medical attention. If you take too many tablets you will probably feel light-headed or dizzy, or you may faint.

#### 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 FIBSOL?

### Things you should do

Have your blood pressure checked when your doctor says to make sure FIBSOL is working.

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

- feel any light-headedness or dizziness after you take your first dose of FIBSOL or if your dose is increased
  - This is especially important if you are taking FIBSOL for heart failure
- feel light-headed, dizzy or faint, and this problem gets worse or continues
  - Get up slowly when getting out of bed or standing up
  - You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This is because your blood pressure is falling suddenly.
  - 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
- Become pregnant while taking FIBSOL
- are about to be started on any new medicine
- plan to have a surgery (even at the dentist) that needs a general anaesthetic
  - Your blood pressure may drop suddenly during surgery
- have excessive vomiting and/or diarrhoea while taking FIBSOL
  - This can result in you losing too much water and may drop your blood pressure too much

### Things you must do

- Make sure you drink enough water during exercise and hot weather when you are taking FIBSOL, especially if you sweat a lot.
  - If you do not drink enough water while taking FIBSOL, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.
- Go to your doctor regularly for a check-up.
  - Your doctor may occasionally do a blood test to check your potassium level in the blood and see how your kidneys are working.

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

### Things you should not do

- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

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

FIBSOL may cause dizziness in some people, especially after the first dose or if the dose is increased. Make sure you know how you react to FIBSOL before you drive a car,

operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

### Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may advise you to limit your alcohol intake.

### Things that would be helpful for your blood pressure or heart failure

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

- Diet - eat a healthy diet, which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- 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.
- Smoking - your doctor may advise you to stop smoking or at least cut down.
- 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.

### Looking after your medicine

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

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

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

### 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
<p><b>Gut-related:</b></p> <ul style="list-style-type: none"> <li>mild stomach upsets such as feeling sick, diarrhoea, or stomach pains</li> <li>impotence</li> </ul> <p><b>Respiratory or breathing-related:</b></p> <ul style="list-style-type: none"> <li>dry cough</li> <li>running nose or sinus pain</li> <li>changes in the way things smell</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>light-headedness or dizziness</li> <li>headache</li> <li>fatigue</li> <li>hair loss or thinning</li> <li>changes in the way things taste</li> <li>feeling sleepy or difficulty in going to sleep, strange dreams</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>changes in the way our heart beats, for example, if you notice it beating faster</li> <li>yellowing of the skin and/or eyes, also called jaundice</li> <li>tingling or numbness of the hands and feet</li> <li>severe abdominal pain</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>itchy skin rash, psoriasis or other skin problems</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>passing less urine than is normal for you</li> <li>bruising more easily than normal</li> <li>signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness.</li> <li>seeing, feeling or hearing things that are not there</li> </ul>	<p><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></p>

## Very serious side effects

Very serious side effects	What to do
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>chest pain, angina</li> <li>swelling of the face, lips, mouth, tongue or throat, which may</li> </ul>	<p><b>Stop taking this medicine and tell your doctor immediately, or go to the</b></p>

<ul style="list-style-type: none"> <li>cause difficulty in swallowing or breathing.</li> <li>wheeziness due to tightness in the chest, difficulty breathing</li> <li>collapse, numbness or weakness of arms or legs</li> <li>pinkish, itchy swellings on the skin, also called hives or nettle rash</li> <li>fainting</li> </ul>	<p><b>Emergency Department at your nearest hospital.</b></p>
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**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 FIBSOL contains

<b>Active ingredient (main ingredient)</b>	lisinopril (as dihydrate)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>calcium hydrogen phosphate dihydrate</li> <li>colloidal anhydrous silica</li> <li>Mannitol</li> <li>maize starch</li> <li>magnesium stearate</li> <li>pregelatinized maize starch</li> </ul>
<b>Potential allergens</b>	None

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

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

### What FIBSOL looks like

FIBSOL 5 is off white round tablet, debossed with "L" break-line "5" on one side and plain on other side. (Aust R 101316).

FIBSOL 10 is off white round tablet, debossed with "L" break-line "10" on one side and plain on other side. (Aust R 101317).

FIBSOL 20 is off white round tablet, debossed with "L" break-line "20" on one side and plain on other side. (Aust R 101318).

### **Who distributes FIBSOL**

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121  
Australia  
[www.arrotex.com.au](http://www.arrotex.com.au)

This leaflet was prepared in January 2025.