

# Fenofibrate Sandoz®

## 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 Fenofibrate Sandoz?

Fenofibrate Sandoz contains the active ingredient fenofibrate. Fenofibrate Sandoz is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood. For more information, see Section [1. Why am I using Fenofibrate Sandoz?](#) in the full CMI.

### 2. What should I know before I use Fenofibrate Sandoz?

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

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

Some medicines may interfere with Fenofibrate Sandoz 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 Fenofibrate Sandoz?

- The initial recommended dose is 145 mg daily, taken as 1 x 145 mg tablet, your doctor may prescribe a lower dose if you have kidney problems.

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

### 5. What should I know while using Fenofibrate Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, surgery, dentist or pharmacist you visit that you are using Fenofibrate Sandoz.</li><li>Tell your doctor if you have these medical conditions: kidney problems, muscular aching, tenderness or weakness not caused by exercise.</li><li>Tell your doctor if you become pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not stop using this medicine suddenly.</li><li>Do not take Fenofibrate Sandoz if you have an allergy to any fibrates (such as gemfibrozil) and ketoprofen.</li><li>Do not take this medicine if you are pregnant or breastfeeding.</li><li>Do not take this medicine if you have liver disease, severe kidney disease, disease of the gallbladder or pancreas, experienced muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.</li><li>Do not take this medicine if you are taking another fibrate.</li><li>Do not take this medicine if you are allergic to peanuts, peanut oil, soy lecithin or related products.</li><li>Do not give Fenofibrate Sandoz to anyone under the age of 18 years.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how Fenofibrate Sandoz affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>Avoid drinking large quantities of alcohol while you are taking this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep the medicine in a cool, dry place where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

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.

# Fenofibrate Sandoz®

Active ingredient(s): *fenofibrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fenofibrate Sandoz. **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 Fenofibrate Sandoz.**

**Where to find information in this leaflet:**

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

### 1. Why am I using Fenofibrate Sandoz?

**Fenofibrate Sandoz contains the active ingredient fenofibrate.** Fenofibrate Sandoz belongs to a group of medicines known as fibric acid derivatives.

Fenofibrate Sandoz works through the activation of a cell nuclear receptor called PPAR $\alpha$ , which reduces the amount of triglycerides and bad cholesterol made in the body and increases the good cholesterol.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol becomes too high.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed.

Over time, this can form hard areas (called plaque) on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack and angina), and stroke.

Cholesterol is carried through the body by different proteins, LDL and HDL. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

In most patients, Fenofibrate Sandoz reduces the bad cholesterol and can actually raise the good cholesterol.

Patients with type 2 diabetes may have some level of diabetic retinopathy, a complication of diabetes that may lead to vision loss or impairment. Fenofibrate Sandoz has

been shown to slow the progression of diabetic retinopathy in patients diagnosed with this condition.

Fenofibrate Sandoz does not reduce the cholesterol that comes from fat in food.

Therefore, when you are taking Fenofibrate Sandoz, you also need to follow a low fat diet and other measures, such as exercise and weight control.

**Fenofibrate Sandoz is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood.**

### 2. What should I know before I use Fenofibrate Sandoz?

#### Warnings

**Do not use Fenofibrate Sandoz if:**

- you are allergic to fenofibrate, any fibrates (such as gemfibrozil) or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing. Always check the ingredients to make sure you can use this medicine.
- you are taking another fibrate.
- you are allergic to soya lecithin.
- it is after the expiry date printed on the pack or if the packaging is damaged or show signs of tampering.

**Check with your doctor if you:**

- have any other medical conditions:
  - liver disease
  - severe kidney disease
  - disease of the gallbladder or pancreas
  - experienced muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- take any medicines for any other condition
- have any allergies to any other medicines, foods, preservatives or dyes.

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.

It may affect your developing baby if you take it during pregnancy.

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

The active ingredient in Fenofibrate Sandoz passes into breast milk and there is a possibility your baby may be affected.

### 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 Fenofibrate Sandoz and affect how it works.

- oral anti-coagulants (medicines used to prevent blood clots)
- other cholesterol regulating medicines including fibrates
- ciclosporin (a medicine which suppresses the immune system)
- glitazones (medicines to reduce sugar levels)

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

### 4. How do I use Fenofibrate Sandoz?

#### How much to take

- The initial recommended dose is 145 mg daily, taken as 1 x 145 mg tablet, your doctor may prescribe a lower dose if you have kidney problems.

#### When to take Fenofibrate Sandoz

- Fenofibrate Sandoz can be taken at any time of the day, with or without food. Any dietary measures started before treatment with Fenofibrate Sandoz should be continued.

#### How to take Fenofibrate Sandoz

- Swallow the tablet(s) whole with a full glass of water.

#### How to long to take Fenofibrate Sandoz

- Follow the instructions provided and use Fenofibrate Sandoz until your doctor tells you to stop.

#### If you forget to use Fenofibrate Sandoz

Fenofibrate Sandoz 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, and then go back to taking your medicine as you would normally.

**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.**

- These may increase the chance of getting an unwanted side effect.

#### If you use too much Fenofibrate Sandoz

If you think that you have used too much Fenofibrate Sandoz, 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.

Symptoms of an overdose may include:

- diarrhoea
- nausea

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

### 5. What should I know while using Fenofibrate Sandoz?

#### Things you should do

**Have your blood fats checked when requested by your doctor to make sure Fenofibrate Sandoz is working.**

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

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

- become pregnant while you are taking this medicine.

Remind any doctor, surgery, dentist or pharmacist you visit that you are using Fenofibrate Sandoz.

#### Things you should not do

- Do not stop using this medicine suddenly.
- Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not give Fenofibrate Sandoz to anyone under the age of 18 years.

#### Driving or using machines

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

Fenofibrate Sandoz may cause dizziness in some people.

#### Drinking alcohol

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

Drinking large quantities of alcohol may increase your chance of Fenofibrate Sandoz causing liver problems.

#### Things that may help you reduce the chance of coronary heart disease

Lowering high cholesterol can help reduce your chances of having Coronary Heart Disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking,

diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause. Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietitian about these measures and for more information.

- Diet - continue the healthy diet recommended by your doctor, dietitian or pharmacist.
- Weight - your doctor may advise you to lose weight if you are overweight.
- Exercise - make exercise a part of your routine – walking is good. Ask your doctor for advice before starting exercise.
- Smoking - your doctor will advise you to stop smoking.

### Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the box or the blister pack they may not keep well.
- Protect from light and moisture.

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

Store it in a cool dry place 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.**

### When to discard your medicine

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

### 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
<ul style="list-style-type: none"> <li>• stomach pain or discomfort</li> <li>• back pain</li> <li>• headache</li> <li>• muscular pain or spasms</li> <li>• unusual tiredness or weakness</li> <li>• diarrhoea or constipation</li> <li>• nausea</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects.</b>

<ul style="list-style-type: none"> <li>• skin reactions, photosensitivity reactions</li> <li>• sexual dysfunction</li> </ul>	<b>effects and they worry you.</b> <b>They are generally mild and do not cause patients to stop taking Fenofibrate Sandoz.</b>
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• difficulty in breathing</li> <li>• severe abdominal pain</li> <li>• chest pain</li> <li>• temporary paralysis of the muscles</li> <li>• yellowing of the skin and eyes and dark coloured urine</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 Fenofibrate Sandoz contains

Active ingredient (main ingredient)	fenofibrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> <li>• sucrose</li> <li>• hypromellose</li> <li>• sodium lauryl sulfate</li> <li>• lactose monohydrate</li> <li>• croscarmellose sodium</li> <li>• microcrystalline cellulose</li> <li>• magnesium stearate</li> <li>• Opadry AMB complete film coating system 80W68912 white (PI 12258).</li> </ul>

<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• sucrose</li><li>• sugars as lactose</li><li>• soya lecithin</li></ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Fenofibrate Sandoz looks like**

Fenofibrate Sandoz 145 mg – White to off white, oval, biconvex film coated tablets, debossed with J on one side and 136 on the other side. Pack size of 30 tablets (Aust R 280720).

### **Who distributes Fenofibrate Sandoz**

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Tel: 1800 726 369

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