

Fenofibrate Lupin

Consumer Medicine Information (CMI) Summary [optional]

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 Lupin?

Fenofibrate Lupin contains the active ingredient fenofibrate. Fenofibrate Lupin helps to regulate cholesterol and triglycerides, which are fat-like substances in the blood.

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

2. What should I know before I use Fenofibrate Lupin?

Do not use if you have ever had an allergic reaction to fenofibrate, any other any fibrates (such as gemfibrozil), ketoprofen, or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist 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 Lupin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fenofibrate Lupin 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 take Fenofibrate Lupin?

- Swallow the tablets whole with a full glass of water.
- The initial recommended dose is 145 mg daily, taken as 1 tablet daily. 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 Lupin?](#) in the full CMI.

5. What should I know while taking Fenofibrate Lupin?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Fenofibrate Lupin.• Tell your doctor if you have these medical conditions: kidney problems, muscular aching, tenderness or weakness not caused by exercise.• Tell your doctor if you become pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly.• Do not take Fenofibrate Lupin if you have an allergy to any fibrates (such as gemfibrozil) and ketoprofen.• Do not take this medicine if you are pregnant or breastfeeding.• 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.• Do not take this medicine if you are taking another fibrate.• Do not give Fenofibrate Lupin to anyone under the age of 18 years.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how this medicine affects you.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking large quantities of alcohol while you are taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep your medicine in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Fenofibrate Lupin?](#) 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 Lupin

Active ingredient(s): fenofibrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Fenofibrate Lupin. **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 Lupin.**

Where to find information in this leaflet:

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

1. Why am I using Fenofibrate Lupin?

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

Fenofibrate Lupin works through the activation of a cell nuclear receptor called PPAR α , 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.

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

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 reduces the bad cholesterol and can actually raise the good cholesterol. It does not reduce the cholesterol that comes from fat in food.

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

2. What should I know before I use Fenofibrate Lupin?

Warnings

Do not use Fenofibrate Lupin if you:

- are allergic to fenofibrate, any other any fibrates (such as gemfibrozil), ketoprofen, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include:
 - shortness of breath, wheezing or difficulty breathing;
 - swelling of the face, lips, tongue or other parts of the body;
 - rash, or itching or hives on the skin.
- are currently taking another fibrate drug (eg. gemfibrozil).

Check with your doctor or pharmacist if you:

- have any other medical conditions, such as:
 - liver disease;
 - severe kidney disease;
 - disease of the gallbladder or pancreas;
 - muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides, not caused by exercise.
- 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

Do not use Fenofibrate Lupin if you are pregnant. Check with your doctor if you intend to become pregnant.

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

Do not breastfeed if you are taking this medicine.

Fenofibrate passes into breast milk and there is a possibility that 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 Lupin and affect how it works.

These include:

- oral anti-coagulants, medicines used to prevent blood clots;
- other cholesterol regulating medicines including fibrates;
- ciclosporin, a medicine which suppresses the immune system;
- glitazones, used 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 Lupin.

4. How do I take Fenofibrate Lupin?

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.
- Follow the instructions provided and take Fenofibrate Lupin until your doctor tells you to stop.

When to take Fenofibrate Lupin

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

How to take Fenofibrate Lupin

- Swallow the tablets whole with a full glass of water.

If you forget to take Fenofibrate Lupin

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

If you take too much Fenofibrate Lupin

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

Symptoms of an overdose may include diarrhoea and nausea.

5. What should I know while taking Fenofibrate Lupin?

Things you should do

- **Have your blood fats checked when requested by your doctor to make sure Fenofibrate Lupin is working.**
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

Call your doctor straight away if you:

- become pregnant while taking this medicine.
- start breastfeeding while taking this medicine.

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

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 your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your Fenofibrate Lupin or change the dosage without checking with your doctor.
- Do not give Fenofibrate Lupin to anyone under the age of 18 years.

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:

- **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.

Talk to your doctor, pharmacist or dietitian about these measures and for more information.

Driving or using machines

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

Fenofibrate Lupin 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 causing liver problems.

Avoid drinking large quantities of alcohol while you are taking this medicine.

Looking after your medicine

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

Follow the instructions on 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.

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
Gastrointestinal system: <ul style="list-style-type: none"> • Stomach pain or discomfort. • Diarrhoea or constipation. • Nausea. Muscular system: <ul style="list-style-type: none"> • Back pain. • Muscular pain or spasms. 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
Skin and skin structures: <ul style="list-style-type: none"> • Skin reactions. • Photosensitivity reactions. Reproductive system: <ul style="list-style-type: none"> • Sexual dysfunction. General: <ul style="list-style-type: none"> • Headache. • Unusual tiredness or weakness. 	[Insert appropriate action]

Serious side effects

Serious side effects	What to do
Gastrointestinal system: <ul style="list-style-type: none"> • Severe abdominal pain. Muscular system: <ul style="list-style-type: none"> • Temporary paralysis of the muscles. • Yellowing of the skin and eyes. Respiratory system: <ul style="list-style-type: none"> • Difficulty in breathing. Urinary system: <ul style="list-style-type: none"> • Dark coloured urine. General: <ul style="list-style-type: none"> • Chest pain. 	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.

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. 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 Lupin contains

Active ingredient (main ingredient)	Fenofibrate
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Other ingredients (inactive ingredients)	Sucrose Hypromellose Sodium lauryl sulfate Lactose monohydrate Crospovidone Polacrillin potassium Colloidal anhydrous silica Purified water Magnesium stearate The film-coating contains: Polyvinyl alcohol Titanium dioxide Purified talc Macrogol 6000 Macrogol 3350 Iron oxide yellow (48 mg tablets only)
Potential allergens	Lactose monohydrate Sucrose

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

What Fenofibrate Lupin looks like

Fenofibrate Lupin 48 mg is a yellow coloured, oval-shaped, film-coated tablet debossed with “48” on one side and “FB” on the other side (AUST R 319524).

Fenofibrate Lupin 145 mg is a white to off-white coloured, oval-shaped, film-coated tablet debossed with “145” on one side and “FB” on the other side (AUST R 319522).

Who distributes Fenofibrate Lupin

Generic Health Pty Ltd

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This leaflet was prepared in January 2025.