

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking LIPIGEM?

LIPIGEM contains the active ingredient gemfibrozil. LIPIGEM is used in patients with pancreatitis (inflammation of the pancreas) to lower very high levels of triglycerides when strict diet control has not been adequate. It can also be used to control fats in the blood in diabetic patients, and reduce the risk of heart diseases such as angina and heart attacks in patients with high levels of cholesterol. For more information, see Section [1. Why am I taking LIPIGEM?](#) in the full CMI.

2. What should I know before I take LIPIGEM?

Do not take if you have ever had an allergic reaction to gemfibrozil 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 take LIPIGEM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LIPIGEM 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 LIPIGEM?

- The normal dose of LIPIGEM is one 600 mg tablet twice a day.
- Take one tablet in the morning and one in the evening. The tablets are best taken on an empty stomach, half an hour before food.

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

5. What should I know while taking LIPIGEM?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking LIPIGEM. • Tell your doctor if you are pregnant, breast-feeding, or are thinking about becoming pregnant.
Things you should not do	• Do not take LIPIGEM to treat any other complaints unless your doctor tells you to. • Do not give LIPIGEM to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how LIPIGEM affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. Excessive alcohol intake can raise your cholesterol levels or affect your liver function, which could increase the chance of you getting unwanted side effects.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. • Keep your tablets in the bottle until it is time to take them.

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

6. Are there any side effects?

Less serious side effects: heartburn, pain in the stomach, feeling sick (nausea), vomiting, skin rash, constipation, change in taste, diarrhoea, tiredness, dizziness, headache, depression, decreased libido, tingling in the hands or feet.

Serious side effects: painful, weak or tender muscles, signs of kidney disease such as passing little or no urine, signs of anaemia, such as tiredness, being short of breath and looking pale, signs of frequent infections such as fever, chills, sore throat or mouth ulcers, signs of liver disease such as yellowing of the skin and eyes and dark coloured urine.

Very serious side effects: swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing and breathing, temporary paralysis or weakness of muscles, very strong and sudden pain in the upper right part of the abdomen, recurrent painful attacks for several hours after meals, abdominal bloating (inflammation of the gall bladder).

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.

LIPIGEM®

Active ingredient: *gemfibrozil*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LIPIGEM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LIPIGEM.**

Where to find information in this leaflet:

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

1. Why am I taking LIPIGEM?

LIPIGEM contains the active ingredient gemfibrozil. It belongs to a group of medicines called fibric acid derivatives or fibrates.

LIPIGEM helps to lower high triglycerides, cholesterol and other fats. It should be used in conjunction with a low fat diet.

LIPIGEM is used in patients with pancreatitis (inflammation of the pancreas) to lower very high levels of triglycerides when strict diet control has not been adequate.

LIPIGEM can also be used to control fats in the blood in diabetic patients, and reduce the risk of heart diseases such as angina and heart attacks in patients with high levels of cholesterol.

The exact way in which LIPIGEM works is not known, but it is thought to reduce the amount of triglycerides made in the body. In most patients, LIPIGEM reduces the 'bad' cholesterol and triglycerides and can actually raise the 'good' cholesterol.

What is cholesterol and triglycerides

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body. Cholesterol has many functions; these include building cell membranes, making bile acids (which help digest food) and producing some essential hormones. However, too much cholesterol can be a problem.

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 levels become too high.

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

There are different types of cholesterol. 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.

When you have high levels of 'bad' cholesterol in your blood, it may begin to '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 may become hard deposits, also called plaque, on the lining of your blood vessels, making it more difficult for the blood to flow through the narrowed space. Sometimes, the plaque can detach from the vessel wall and float in the bloodstream; it can then reach a smaller vessel and completely block it. This blocking of your blood vessels can lead to several types of blood vessel diseases, heart attack, angina and stroke.

There is another type of blood fat called triglyceride which is a source of energy. However, high levels of triglyceride can be associated with a low level of "good" cholesterol and may increase your risk of heart disease.

LIPIGEM does not reduce the cholesterol that comes from fat in food. Therefore, when you are taking LIPIGEM, you also need to follow a low fat diet and other measures, such as exercise and weight control.

In most people, there are no symptoms of high triglyceride or cholesterol levels. Your doctor can measure your levels with a simple blood test.

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

Your doctor may have prescribed it for another reason.

LIPIGEM is not addictive.

2. What should I know before I take LIPIGEM?

Warnings

Do not take LIPIGEM if:

- you are allergic to gemfibrozil, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- Always check the ingredients to make sure you can take this medicine.
- you are taking medicine to treat diabetes such as repaglinide or rosiglitazone
- you are taking medicines containing simvastatin which is used to control cholesterol
- you have severe liver disease
- you have severe kidney disease

- you have gallstones or gallbladder disease
- you have experienced an increased sensitivity to the sun while taking a medicine called fibrates, a type of medicine used to prevent heart disease

Symptoms of photosensitivity are sunburn (redness, itching, swelling and blistering of your skin) much quicker than normal.

- the packaging is torn or shows signs of tampering
- the product is past the expiry date or damaged. If this occurs, return it to your pharmacist.

Talk to your doctor if you are not sure whether you should start taking LIPIGEM.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- have or have had any of the following medical conditions:
 - o liver problems
 - o kidney problems
 - o gall stones or gall bladder problems
 - o diabetes
 - o a thyroid condition
 - o muscle pain, tenderness or weakness from other medicines used to treat triglycerides or cholesterol.

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

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 LIPIGEM if you are pregnant or are thinking of getting pregnant.

Do not take LIPIGEM if you are breastfeeding.

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

Use in children

LIPIGEM is not recommended for use in children, as its safety and effectiveness in children have 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 may be affected by LIPIGEM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines which thin your blood such as warfarin. Your doctor may need to adjust the amount of blood thinning medication
- other medicines to treat high triglycerides or cholesterol. Your doctor may choose not to use LIPIGEM together with other prescription medicines for cholesterol lowering
- medicines used to treat diabetes such as repaglinide or rosiglitazones
- medicines used to treat gout such as colchicine
- medicines used for cancer treatment such as bexarotene.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LIPIGEM.

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

4. How do I take LIPIGEM?

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

How much to take

- Your doctor will tell you how many tablets you need to take each day. This may depend on your condition and whether or not you are taking any other medicines.
- The normal dose of LIPIGEM is one 600 mg tablet twice a day.

How to take LIPIGEM

- Swallow LIPIGEM whole with a glass of water or other liquid. Do not crush or chew the tablets.

When to take LIPIGEM

- Take one tablet in the morning and one in the evening.
- The tablets are best taken on an empty stomach, half an hour before food. Taking the tablets half an hour before food means the medicine is absorbed faster into your body. If taking the tablets on an empty stomach makes you feel unwell, you may take them with food.

How long to take LIPIGEM for

- You may have to take this kind of medicine for the rest of your life.
- LIPIGEM helps to regulate your levels of cholesterol and triglycerides. It does not cure your condition. Therefore you must continue to take it as directed by your doctor if you expect to keep your levels controlled. If you stop taking LIPIGEM, your levels may become abnormal again.

If you forget to take LIPIGEM

LIPIGEM should be taken regularly at the same time each day.

If you forget to take a dose, take it as soon as you remember, as long as it is more than 6 hours before your next dose.

If it is less than 6 hours before your next dose, skip the dose you missed. Take your following dose at the normal time.

Talk to your doctor or pharmacist if you are not sure whether to skip the dose or if you have trouble remembering when to take your medicine.

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

If you take too much LIPIGEM

If you think that you or anyone else has taken too much LIPIGEM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking LIPIGEM?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will ask you to have regular blood tests. Your cholesterol and triglyceride levels need to be checked regularly while you are taking this medicine to make sure the medicine is working. Your liver function will also be tested from time to time while you are taking LIPIGEM to prevent unwanted side effects.
- Tell your doctor and pharmacist that you are taking LIPIGEM if you are about to start on any new medicine.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking LIPIGEM.
- Tell your doctor if you are pregnant, breast-feeding, or are thinking about becoming pregnant. If you become pregnant while taking LIPIGEM, stop taking LIPIGEM and contact your doctor immediately.

Things you should not do

- Do not take LIPIGEM to treat any other complaints unless your doctor tells you to.
- Do not give LIPIGEM 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 LIPIGEM affects you.

LIPIGEM generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, LIPIGEM may cause dizziness in some people.

If you feel dizzy, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Excessive alcohol intake can raise your cholesterol levels or affect your liver function, which could increase the chance of you getting unwanted side effects. Your doctor may discuss with you whether you should reduce the amount of alcohol you drink.

Things that would be helpful for your condition

Some self-help measures suggested below may assist your condition. Your doctor or pharmacist can give you more information about these measures.

- **Weight:** While you are taking LIPIGEM, you need to follow a diet plan agreed to with your doctor. This may include measures to lose some weight.
- **Exercise:** Regular exercise can help lower your cholesterol levels. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you experience any discomfort when exercising, see your doctor.
- **Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.

Looking after your medicine

- Store below 25°C.
- Keep your LIPIGEM tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

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 off the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• heartburn • pain in the stomach • feeling sick (nausea) • vomiting • skin rash • constipation • change in taste • diarrhoea • tiredness • dizziness • headache • depression • decreased libido • tingling in the hands or feet	Speak to your doctor if you have any of these less serious side effects and they worry you. These are mild but more frequent side effects of LIPIGEM.

Serious side effects

Serious side effects	What to do
• painful, weak or tender muscles • signs of kidney disease such as passing little or no urine • signs of anaemia, such as tiredness, being short of breath and looking pale • signs of frequent infections such as fever, chills, sore throat or mouth ulcers • signs of liver disease such as yellowing of the skin and eyes and dark coloured urine	Tell your doctor as soon as possible if you notice any of these serious side effects. These are serious but rare side effects. You may need urgent medical attention.

Very serious side effects

Very serious side effects	What to do
• swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing and breathing • temporary paralysis or weakness of muscles • very strong and sudden pain in the upper right part of the abdomen, recurrent painful attacks for several hours after meals, abdominal bloating	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

Very serious side effects	What to do
(inflammation of the gall bladder)	You may need urgent medical attention or hospitalisation.

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.

Some of these side effects (for example, changes in white blood cells, low blood platelet count) can only be found when your doctor does tests from time to time to check your progress.

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 LIPIGEM contains

Active ingredient (main ingredient)	gemfibrozil 600 mg per tablet
Other ingredients (inactive ingredients)	• microcrystalline cellulose • pregelatinised maize starch • crospovidone • hypromellose • polysorbate 80 • colloidal anhydrous silica • magnesium stearate • Opadry White OY-LS-28908 (ID: 2596)
Potential allergens	lactose and trace quantities of sulfites

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

What LIPIGEM looks like

LIPIGEM is a 19 mm x 9.2 mm deep convex, white, film coated oval shaped tablet, debossed "GL600" on one side and Greek alpha symbol on the other. (AUST R 61430).

Each bottle of LIPIGEM contains 60 tablets.

Who distributes LIPIGEM

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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LIPIGEM® is a Viatris company trade mark.

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