

Lipigem

contains the active ingredient gemfibrozil

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Lipigem.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Lipigem against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Lipigem is used for

Lipigem is used to help control high levels of cholesterol and triglycerides, which are fat-like substances in the blood.

It belongs to a group of medicines called fibric acid derivatives or fibrates.

The exact way in which Lipigem works is not known, however it is thought to work by reducing the 'bad' (LDL) cholesterol and triglycerides while raising the 'good' (HDL) cholesterol. This helps keep your blood vessels unblocked and decreases the risk of heart disease to prevent heart attacks, angina and stroke.

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.

Lipigem is available only with a doctor's prescription.

Lipigem is not recommended for use in children, as its safety and effectiveness in children have not been established.

Before you take Lipigem

When you must not take it

Do not take Lipigem if you have an allergy to:

- any medicine containing gemfibrozil
- any of the ingredients listed at the end of this leaflet

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, itching or hives on the skin

Do not take this medicine if you have:

- severe liver diseases
- severe kidney disease
- gallstones or gallbladder disease
- been prescribed a medicine for diabetes such as repaglinide or rosiglitazone
- type I hyperlipoproteinaemia (a specific type of blood fats disorder)

- experienced an increased sensitivity to the sun while taking other fibrates

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

Do not take this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in Lipigem passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- gall stones or gall bladder problems
- diabetes
- thyroid condition

- muscle pain, tenderness or weakness from other medicines used to treat triglycerides or cholesterol

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Lipigem should not be used during pregnancy or while breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking Lipigem.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines interfere with Lipigem. These include:

- medicines used to prevent blood clots such as warfarin. Your doctor may need to adjust the amount of blood thinning medication depending on the blood results (INR).
- medicines used 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.

These 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Lipigem

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet (600 mg) twice a day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it once in the morning and once in the evening, at the same time each day gives you the best effect. This will also help you remember when to take it.

Take Lipigem on an empty stomach, half an hour before food.

Food can interfere with the absorption of Lipigem.

You may take the tablets with food if they upset your stomach when taken before meals.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

Lipigem helps to control high cholesterol and triglycerides levels, but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Lipigem. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea and vomiting, stomach ache, diarrhoea, muscle and joint pain.

While you are taking Lipigem

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Your doctor may do some tests to check your cholesterol and triglyceride levels, your blood and liver function from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind your doctor to periodically conduct blood tests for you.

Things you must not do

Do not take Lipigem to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery 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.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - eating plenty of vegetables and fruit;
 - reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).

- Be active. Progress, over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active.
- Maintain a healthy weight.
- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lipigem.

This medicine helps most people with high cholesterol and triglyceride levels, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- heartburn
- stomach and abdominal (belly) pain
- feeling sick (nausea), vomiting
- change in taste
- diarrhoea or constipation
- tiredness
- dizziness
- headache
- blurred vision
- skin rash
- depression
- decreased sex drive

The above list includes the more common and milder side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of an allergic reaction include swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing
- painful, weak or tender muscles
- tingling in the hands or feet
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- signs of anaemia, such as tiredness, shortness of breath and looking pale
- temporary paralysis or weakness of muscles
- intense 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)
- liver problems can also occur and may be serious. Your doctor may do blood tests to check your liver.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

After taking Lipigem

Storage

Keep your Lipigem in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Lipigem or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Lipigem is a an oblong, white tablet marked "GL600" on one side and a Greek alpha symbol on the other.

Each bottle of Lipigem contains 60 tablets.

Ingredients

- Lipigem contains 600 mg of gemfibrozil as the active ingredient.
- It also contains the following inactive ingredients:
- microcrystalline cellulose
- pregelatinised maize starch
- crospovidone
- hydroxypropylcellulose
- polysorbate
- colloidal anhydrous silica
- magnesium stearate
- macrogol 4000
- hypromellose, lactose
- titanium dioxide (171)

Manufacturer/Supplier

Lipigem is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Cnr. Wentworth Park Road & Bay Street

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Lipigem 600 mg: AUST R 61430

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