

LIPIGEM[®]

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

What LIPIGEM does

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.

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.

How LIPIGEM works

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

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.

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 LIPIGEM or:

- any other medicine containing gemfibrozil, or
- 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:

- **are pregnant, or are thinking of getting pregnant**
- **are breast-feeding.**

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

- **are taking medicine to treat diabetes such as repaglinide or rosiglitazone**
- **are taking medicines containing simvastatin which is used to control cholesterol**
- **have severe liver disease**
- **have severe kidney disease**
- **have gallstones or gallbladder disease**
- **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.

Do not take LIPIGEM if the packaging is torn or shows signs of tampering.

If the product is past the expiry date or damaged, return it to your pharmacist.

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

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
- a thyroid condition
- 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 him/her before you start taking LIPIGEM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath 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.

Tell your doctor about any of the above before you take LIPIGEM.

How to 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.

Ask your doctor or pharmacist for help if you do not understand the instructions on the bottle.

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 it

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

When to take it

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 it

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 it

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 (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. Keep telephone numbers of these places handy.

While you are taking LIPIGEM

Things you must 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 this medicine.

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 must 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.

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.

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

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.
- **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.
- **Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need

medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

Tell your doctor if...

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

- 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

These are mild but more frequent side effects of LIPIGEM.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- 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.

These are serious but rare side effects. You may need urgent medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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).

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) 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 25°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 your tablets where young children cannot reach them.

A locked cupboard at least one-and-a-half metres off 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 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.

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
- hypromellose
- polysorbate 80
- colloidal anhydrous silica
- magnesium stearate
- Opadry White OY-LS-28908 (ARTG PI No: 2596)

LIPIGEM also contains lactose and trace quantities of sulfites.

Supplier

LIPIGEM is supplied in Australia by:

**Alphapharm Pty Ltd trading as
Viatrix**

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

This leaflet was prepared in June
2024.

Australian registration number:
AUST R 61430

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