

AUSGEM[®]

Gemfibrozil (gem-FI-broe-zil)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about *AUSGEM*. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking gemfibrozil against the benefits this medicine is expected to have for you.

Keep this leaflet with your medicine. You may need to read it again.

What is *AUSGEM* used for

The name of your medicine is *AUSGEM*. It contains the active ingredient, gemfibrozil.

AUSGEM belongs to group of medicines known as fibric acid derivatives. *AUSGEM* is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood.

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body for many things, such as making bile acids (which help digest food) and some hormones. However, having too much cholesterol in the blood can contribute to the development of heart disease.

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 you obtain from your food, 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, this fat 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 a “plaque”) on the lining 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.

There are different types of cholesterol, called LDL and HDL. LDL cholesterol is the harmful or “bad” cholesterol that can block your blood vessels. HDL cholesterol is the beneficial or “good” cholesterol that is thought to remove the LDL (“bad”) cholesterol from the blood vessels.

High levels of triglycerides may also increase your risk of heart disease, as these fats can be associated with a low level of the beneficial or “good” cholesterol.

In most patients, *AUSGEM* reduces the bad cholesterol and increases the good cholesterol.

AUSGEM does **not** reduce the cholesterol that comes from the fat in food.

Therefore, when you are taking *AUSGEM*, 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 cholesterol. Your doctor can measure your cholesterol with a simple blood test.

The exact way in which *AUSGEM* works is not known, but it is thought to work by reducing the amount of triglycerides made in the body.

Your doctor will have explained to you why you are being treated with *AUSGEM*.

Follow all the directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may have prescribed *AUSGEM* for another reason. Ask your doctor if you want more information about why this medicine has been prescribed for you.

There is no evidence that *AUSGEM* is addictive.

Before you take *AUSGEM*

You should not take *AUSGEM* if:

- You are allergic to the medicine, “gemfibrozil” or any of the ingredients listed under the “Product description” section.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.

- You have severe liver disease.
- You have severe kidney disease.
- You have gall bladder disease.
- You are pregnant or breast-feeding.

Your baby may absorb this medicine in the womb or from breast milk and there is a possibility that this may be harmful to the baby.

- You have a lipid disorder called "type I hyperlipoproteinaemia".
- You have had muscle pain, tenderness or weakness from other medicines that treat high cholesterol or triglycerides.
- You are taking the drug cerivastatin (i.e. 'Kazak' or 'Lipobay').
- You are taking the drug repaglinide (i.e. 'NovoNorm').

Do not use *AUSGEM* if the packaging is torn or shows signs of tampering.

Do not use this medicine if the expiry date on the pack has passed.

If you take the medicine after the expiry date has passed, it may make you unwell.

This medicine is not suitable for children.

You should tell your doctor if:

- You intend to become pregnant or breast-feed during the course of your treatment.
- You suffer from any other medical condition which your doctor does not know about, including thyroid problems or diabetes.
- You are on any other medications. If you are taking medicines to "thin" the blood, the dose of these medicines may need to be adjusted. If you are taking another medication to lower the fats in your blood, you should tell your doctor, as *AUSGEM* may not be suitable with these medicines.

You should also tell your doctor about any other medicines that you have bought without a prescription from either your pharmacy, the supermarket or health food shop.

How to use *AUSGEM*

The label on your *AUSGEM* bottle will tell you how to take your medication and how often. If this is not the case, or you are unclear about the directions, ask your doctor or pharmacist to write down the directions.

The directions given to you by your doctor or pharmacist may differ from the information in this leaflet.

However, the usual dose of *AUSGEM* to regulate the fats in your blood is ONE tablet twice a day. The tablet should be taken with a glass of water half an hour before breakfast and half an hour before the evening meal.

It is important to take your medicine regularly. If you miss a dose, take it when you remember. However, if it is nearly time for your next

dose, you can skip the missed dose and continue to take your next tablet at the usual time.

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

AUSGEM helps lower your cholesterol and triglyceride levels. It does not cure your condition. You must continue to take *AUSGEM* for as long as your doctor recommends.

If you stop taking your medication before your doctor tells you to, your cholesterol and triglyceride levels may rise again. Some people need to take medicines to lower their fat levels for the rest of their lives.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much *AUSGEM*. 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.

If you take too much *AUSGEM* you may have the following symptoms: abdominal cramps, nausea, vomiting and diarrhoea.

While you are taking *AUSGEM*

Your doctor will ask you to have blood tests while you are taking *AUSGEM*. This is to check on a number of conditions including your fat levels. This is the way your doctor will know if *AUSGEM* is working for you.

The blood tests will also tell your doctor if *AUSGEM* is affecting your blood or liver. In some patients, this medication can affect your blood cells which may cause anaemia or make you more prone to infection. *AUSGEM* may also affect your liver.

Although these unwanted effects only occur in some patients and are generally temporary, it is important that you help your doctor check on your health by keeping these appointments.

If you become pregnant while you are taking *AUSGEM*, contact your doctor immediately.

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

Do not use *AUSGEM* to treat any other complaints unless your doctor tells you to.

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase the chance of *AUSGEM* causing you liver problems.

Be careful driving or operating machinery until you know how *AUSGEM* affects you. *AUSGEM* generally does not cause any problems with your ability to drive a car or operate machinery. However, as with any medicine, *AUSGEM* may cause dizziness in some people.

Side effects

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

AUSGEM helps most people with high levels of cholesterol and triglycerides, but it may

have unwanted side effects in a few people.

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 following lists 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 you notice any of the following and they worry you:

- weakness
- confusion
- feeling depressed or sad
- dizziness
- sleepiness
- aching muscles, muscle tenderness or weakness, not caused by exercise
- painful, swollen joints
- tiredness
- headache
- skin rash
- change in taste
- nausea and/or vomiting
- heartburn
- stomach pains
- diarrhoea
- constipation
- blurred vision or eyesight
- increase in the number of infections such as colds or bladder infections
- decreased interest in sex or inability to have sexual intercourse
- swelling with fluid in tissues
- swelling around the neck

Tell your doctor immediately if you notice any of the following:

- increased feeling or sensitivity, especially on the skin
- pinkish, itchy swellings on the skin, also called hives or nettle rash

- yellowing of the skin and/or eyes (this may be related to jaundice)
- tingling or numbness in the hands or feet, also known as 'pins and needles'
- spinning sensation (vertigo)
- sudden onset of severe stomach pain in the lower right hand side of the stomach with tenderness or muscle tightness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

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

- signs of anaemia, such as tiredness, being short of breath, dizziness and looking pale
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

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

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

After using *AUSGEM*

Storage

Keep your *AUSGEM* tablets in the bottle until it is time to take them.

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

Keep your *AUSGEM* tablets in a cool dry place where

the temperature stays below 30°C.

Do not store *AUSGEM* or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

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 above the ground is a good place to store medicines.

Disposal

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

This is not all the information that is available on *AUSGEM*. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product description

AUSGEM is presented as a white, film-coated, oval, biconvex tablet with "GEMFIB" and half score on one side and "600" on the other side.

In addition to the active ingredient "gemfibrozil", the tablets also contain:

- povidone
- polysorbate 80
- crospovidone
- starch-pregelatinised maize
- cellulose-microcrystalline
- silica-colloidal anhydrous
- croscarmellose sodium
- magnesium stearate
- sodium lauryl sulfate

The tablet coating contains:

- polydextrose
- hypromellose
- titanium dioxide

- triacetin
- polyethylene glycol

***AUSGEM* does not contain any gluten, lactose, sucrose, tartrazine or other azo dyes.**

Supplier

Sigma Pharmaceuticals Pty Ltd
(A.C.N.004 118 594)
96 Merrindale Drive
Croydon VIC 3136

Telephone: 03 - 9839 2800

The registration number for *AUSGEM* tablets is AUST R 62099.

The CMI was prepared on 22 September 1997, updated in March'01, June'01, July 2001 & October'03.