

# AUSGEM

## Consumer Medicine Information (CMI) summary

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 taking AUSGEM?

AUSGEM contains the active ingredient gemfibrozil. AUSGEM is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood.

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

### 2. What should I know before I take AUSGEM?

Do not use 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 AUSGEM?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with AUSGEM 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 AUSGEM?

- 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.

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

### 5. What should I know while using AUSGEM?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using AUSGEM.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give AUSGEM to anyone else, even if they have the same condition as you.</li><li>• Do not take AUSGEM to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how AUSGEM affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Avoid drinking large quantities of alcohol. Drinking large quantities of alcohol may increase the chance of AUSGEM causing you liver problems.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li><li>• Keep your tablets in the bottle until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

Common side effects includes: • 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. Serious side effects includes: 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, tingling or numbness in the hands or feet, spinning sensation, 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. Very serious side effects: 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.

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.

# AUSGEM

Active ingredient(s): gemfibrozil

## Consumer Medicine Information (CMI)

This leaflet provides important information about using AUSGEM. **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 AUSGEM.**

Where to find information in this leaflet:

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

## 1. Why am I taking AUSGEM?

**AUSGEM 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.

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.

## 2. What should I know before I take AUSGEM?

### Warnings

**Do not take AUSGEM if:**

- you are allergic to gemfibrozil, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of 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
- 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’).

**This medicine is not suitable for children.**

**Check with your doctor if you:**

- suffer from any other medical condition which your doctor does not know about, including thyroid problems or diabetes.
- take any medicines for any other condition. 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.

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**

Check with your doctor if you are pregnant or breast-feed during the course of your treatment. 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.

### **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.

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

### **4. How do I take AUSGEM?**

#### **How much to take**

- The usual dose of AUSGEM to regulate the fats in your blood is ONE tablet twice a day.
- Follow the instructions provided and use AUSGEM until your doctor tells you to stop.

#### **When to take AUSGEM**

- AUSGEM tablet should be taken with a glass of water half an hour before breakfast and half an hour before the evening meal.

#### **If you forget to take AUSGEM**

**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.**

AUSGEM helps lower your cholesterol and triglyceride levels. It does not cure your condition. You must continue to take this medicine 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 use too much AUSGEM**

If you think that you have used too much AUSGEM, 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.**

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

### **5. What should I know while taking AUSGEM?**

#### **Things you should do**

- Follow all the directions given to you by your doctor carefully. Your doctor may have prescribed this medicine for another reason
- Remind any doctor, dentist or pharmacist you visit that you are using AUSGEM.

#### **While you are taking it**

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 the medicine 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. This medicine 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.

#### **Call your doctor straight away if you:**

- If you become pregnant while you are taking AUSGEM

#### **Things you should not do**

- Do not give AUSGEM to anyone else, even if they have the same condition as you.
- Do not use it to treat any other complaints unless your doctor tells you to.
- 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.

#### **Driving or using machines**

**Be careful before you drive or use any machines or tools 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, it may cause dizziness in some people.

#### **Drinking alcohol**

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

## Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Keep your tablets in the bottle until it is time to take them.

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.

**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
<ul style="list-style-type: none"> <li>• weakness</li> <li>• confusion</li> <li>• feeling depressed or sad</li> <li>• dizziness</li> <li>• sleepiness</li> <li>• aching muscles, muscle tenderness or weakness, not caused by exercise</li> <li>• painful, swollen joints</li> <li>• tiredness</li> <li>• headache</li> <li>• skin rash</li> <li>• change in taste</li> <li>• nausea and/or vomiting</li> <li>• heartburn</li> <li>• stomach pains</li> <li>• diarrhoea</li> <li>• constipation</li> <li>• blurred vision or eyesight</li> <li>• increase in the number of infections such as colds or bladder infections</li> <li>• decreased interest in sex or inability to have sexual intercourse</li> <li>• swelling with fluid in tissues</li> <li>• swelling around the neck</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• increased feeling or sensitivity, especially on the skin</li> <li>• pinkish, itchy swellings on the skin, also called hives or nettle rash</li> <li>• yellowing of the skin and/or eyes (this may be related to jaundice)</li> <li>• tingling or numbness in the hands or feet, also known as 'pins and needles'</li> <li>• spinning sensation (vertigo)</li> <li>• sudden onset of severe stomach pain in the lower right hand side of the stomach with tenderness or muscle tightness</li> <li>• signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of these side effects which are serious and may require medical attention.</b></p>

## Very Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• signs of anaemia, such as tiredness, being short of breath, dizziness and looking pale</li> <li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing</li> <li>• 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</li> </ul>	<p><b>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.</b></p>

**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](http://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 AUSGEM contains

<b>Active ingredient (main ingredient)</b>	gemfibrozil
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• colloidal anhydrous silica</li><li>• croscarmellose sodium</li><li>• crospovidone</li><li>• hypromellose</li><li>• macrogol 8000</li><li>• magnesium stearate</li><li>• microcrystalline cellulose</li><li>• polydextrose</li><li>• polysorbate 80</li><li>• povidone</li><li>• pregelatinized maize starch</li><li>• sodium lauryl sulphate</li><li>• titanium dioxide</li><li>• triacetin</li></ul>
<b>Potential allergens</b>	-

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

### What AUSGEM looks like

AUSGEM is a white, oval, biconvex, film-coated tablet scoreline on one side and plain on the other. (Aust R 62099).

### Who distributes AUSGEM

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121  
Australia  
[www.arrotex.com.au](http://www.arrotex.com.au)

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