

# Gemhexal®

*gemfibrozil tablets*

## Consumer Medicine Information

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Gemhexal.

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 this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

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

### WHAT GEMHEXAL IS USED FOR

This medicine is used to lower high cholesterol, triglycerides and other fats in the blood.

Gemhexal does not reduce the cholesterol that comes from fat in food. Therefore, other measures such as a low fat diet, exercise and weight control need to be followed.

It contains the active ingredient gemfibrozil.

Gemfibrozil belongs to a group of medicines called fibric acid derivatives (fibrates).

It is not exactly known how gemfibrozil works. It is thought to work by lowering "bad" (LDL) cholesterol and triglyceride levels while raising "good" (HDL) cholesterol. Lowering "bad" cholesterol and triglyceride levels helps to keep your blood vessels unblocked. This reduces the risk of heart and blood vessel disease, heart attacks, angina and strokes.

**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.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

### BEFORE YOU TAKE GEMHEXAL

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- gemfibrozil, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines.

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 or have had any of the following medical conditions:**

- liver problems
- severe kidney problems
- gallstones or gall bladder disease
- Type I hyperlipoproteinaemia, a rare enzyme condition where you have high levels of fat in the blood
- increased sensitivity to the sun resulting in allergic reactions (photoallergy) during treatment with fibrates.

**Do not take this medicine if you are also taking any of the following medicines:**

- repaglinide or rosiglitazone, a medicine used to treat diabetes
- cerivastatin (Lipobay), a medicine used to lower cholesterol levels.

**Do not take this medicine if you are pregnant.**

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

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Gemhexal may pass 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:**

- diabetes
- liver problems
- kidney problems
- gallstones or gall bladder problems
- a thyroid condition
- muscle pain, tenderness or weakness from other medicines used to treat high levels of cholesterol or triglycerides
- jaundice, yellowing of the skin and/or eyes.

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

*Taking other medicines*

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

Some medicines and Gemhexal may interfere with each other. These include:

- other fibrates, such as fenofibrate
- other medicines used to treat high cholesterol or triglyceride levels. Examples include atorvastatin, simvastatin, fluvastatin, pravastatin, cerivastatin and colestipol
- medicines used to treat diabetes, such as repaglinide, rosiglitazone, other oral antidiabetic medicines or insulin
- warfarin, a medicine used to prevent blood clots
- bexarotene, a medicine used to treat some cancers.

These medicines may be affected by Gemhexal 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 GEMHEXAL

---

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

They may differ from the information contained in this leaflet.

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

*How much to take*

The usual dose for this medicine is one tablet twice a day, one tablet in the morning and one tablet in the evening.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Gemhexal may not work as well and your problem may not improve.

*How to take it*

Swallow the tablets whole with a full glass of water.

*When to take Gemhexal*

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**The tablets are best taken on an empty stomach, half an hour before food.**

Food can interfere with the absorption of this medicine.

However, if taking the tablets on an empty stomach makes you feel unwell, you may take them with food.

*How long to take Gemhexal*

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

*If you forget to take it*

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

If it is less than 6 hours before 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 that 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 Gemhexal. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include abdominal cramps, diarrhoea, joint and muscle pain, nausea and vomiting.

---

## WHILE YOU ARE TAKING GEMHEXAL

---

### *Things you must do*

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

**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.**

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

Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects such as liver or blood problems.

### *Things you must not do*

**Do not take Gemhexal 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 Gemhexal affects you.**

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness may be worse.

---

## SIDE EFFECTS

---

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

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 lists 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:**

- stomach and abdominal pain
- heartburn
- constipation or diarrhoea
- nausea (feeling sick) and/or vomiting
- tiredness, dizziness, headache
- changes in taste
- decreased libido
- skin rash
- depression.

These are mild but more common side effects of the medicine.

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

- 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
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- severe pain, discomfort and bloating in the abdomen
- painful, weak or tender muscles or joints
- tingling in the hands or feet

- signs of kidney and liver problems, such as passing little or no urine
- temporary paralysis or weakness of muscles.

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

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

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

---

## AFTER TAKING GEMHEXAL

---

### *Storage*

**Keep your medicine in the original container.**

If you take it out of its original container it may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store Gemhexal 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*

Gemhexal 600mg - white oblong tablets.

Available in blisters and bottles of 60 tablets.

### *Ingredients*

Active ingredients:

- Gemhexal 600mg - 600mg gemfibrozil.

Inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- hydroxypropylcellulose
- sodium starch glycollate
- magnesium stearate
- polysorbate 80
- colloidal anhydrous silica
- hypromellose
- titanium dioxide
- macrogol 4000.

### *Supplier*

#### **Sandoz Pty Ltd**

ABN 60 075 449 553

19 Harris Street

Pymont NSW 2009

Australia

Tel: 1800 634 500

This leaflet was revised in May 2012.

#### **Australian Register Numbers**

600mg tablets: AUST R 64873

(blisters)

600mg tablets: AUST R 62537

(bottles)