

Package leaflet: Information for the user

GEMFIBROZIL 600 mg TABLETS

Read all of this leaflet carefully before taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Gemfibrozil is and what it is used for
2. What you need to know before you take Gemfibrozil
3. How to take Gemfibrozil
4. Possible side effects
5. How to store Gemfibrozil
6. Contents of the pack and other information

1. What Gemfibrozil is and what it is used for

Gemfibrozil belongs to a group of medicines called lipid lowering agents.

It is used to reduce high fat levels (cholesterol and triglycerides) in the blood and so help in the prevention of coronary heart disease. These tablets should be used along with dieting, exercise and weight reduction.

2. What you need to know before you take Gemfibrozil

Do not take Gemfibrozil:

- if you are allergic to gemfibrozil or any of the other ingredients of this medicine (listed in section 6)
- if you have or have had gall bladder disease, biliary tract disease or gall stones
- if you have liver or severe kidney problems
- if you have experienced sensitivity to light when previously treated with similar cholesterol lowering drugs
- if you are taking repaglinide (used to treat diabetes).

Warnings and precautions

Talk to your doctor before taking Gemfibrozil:

- if you are over 70 years of age
- if you have an under active thyroid gland or diabetes
- if you have a hereditary muscular disorder or a family history of such problems
- if you have previously suffered from side effects affecting your muscles when taking another cholesterol lowering medicine such as a statin or a fibrate
- if you have problems with alcohol abuse (regularly drinking large amounts of alcohol)
- if you have kidney problems.

Your doctor may carry out liver function and other blood tests.

Other medicines and Gemfibrozil

- Do NOT take **repaglinide** in combination with Gemfibrozil.

Tell your doctor if you are taking, have recently taken or might take any other medicines:

- other drugs to lower your cholesterol e.g. simvastatin, lovastatin, pravastatin or rosuvastatin
- drugs to prevent blood clots (e.g. warfarin)
- rosiglitazone, glimepiride or other drugs for diabetes
- paclitaxel (used to treat cancer)
- bexarotene (used to treat skin cancer)
- drugs known as bile acid sequestrants (a class of drugs that prevents bile acids being reabsorbed from the digestive system, so promoting conversion of cholesterol into bile acids) e.g. colestyramine, colestipol (please see section 3, Taking in combination with a bile acid sequestrant)

Gemfibrozil with food, drink and alcohol

- Keep alcohol intake to a minimum
- Your doctor will have explained the importance of a low fat diet as well as taking Gemfibrozil.

Pregnancy and Breast-feeding

Gemfibrozil is not recommended if you are pregnant or breast-feeding.

If you are pregnant or planning to become pregnant, ask your doctor for advice before taking this medicine.

Driving and using machines

Gemfibrozil may cause dizziness and blurred vision. If affected, do not drive or operate machinery.

3. How to take Gemfibrozil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed preferably with a glass of water.

The recommended dose is:

Adults (including the elderly)

- The normal dosage range is between 900 mg and 1,200 mg (two tablets) each day
- The 1,200 mg dose is taken as one tablet half an hour before breakfast and one tablet half an hour before the evening meal
- The 900 mg dose is taken as a single dose half an hour before the evening meal. Please note that there is a 300 mg product available which is recommended for the 900 mg dosage.

Taking in combination with a bile acid sequestrant

Gemfibrozil may be given in combination with a bile acid sequestrant e.g. colestyramine or colestipol. Gemfibrozil should be taken 2 hours before or after taking your bile acid sequestrant, as the absorption of Gemfibrozil can be affected by these medicines if taken too closely together.

Patients with Kidney problems

If you have mild to moderate kidney problems your doctor may reduce the dose given above. Gemfibrozil should not be used if you have severe kidney problems.

Use in children and adolescents:

Gemfibrozil is not recommended for use in children or adolescents.

If you take more Gemfibrozil than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause stomach pains, diarrhoea, joint and muscle pain, nausea and vomiting. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Gemfibrozil

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for the forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (swelling of the face or tongue or neck, muscle and joint pain, hives, fever, flushing, shortness of breath).
- any unexplained or persistent muscle pain, tenderness, weakness or cramps, especially, if at the same time you feel sick or unwell, are sick, have a high temperature, dark urine, facial swelling or a rapid heart beat. In rare cases (affecting fewer than one person in 1,000) this can progress to become a serious and potentially life threatening condition, called rhabdomyolysis.

Other side effects:

The following side effects have been reported at the approximate frequencies shown:

Very common: may affect more than 1 in 10 people

- heartburn, indigestion.

Common: may affect up to 1 in 10 people

- vertigo, headache
- abdominal pain, diarrhoea, wind, constipation, feeling sick or being sick
- eczema, rash
- fatigue

Uncommon: may affect up to 1 in 100 people

- irregular heart beat.

Rare: may affect up to 1 in 10,000 people

- unusual bleeding or unexplained bruising
- blood disorders that may be characterised by fever or chills, sore throat, ulcers in the mouth or throat
- severe anaemia (a reduction in red blood cells) causing unusual tiredness or weakness

- reduction or increase in white blood cells (leucopenia, eosinophilia), bone marrow disease (bone marrow failure)
- dizziness, sleepiness, pins-and-needles, inflammation or damage of the nerves (peripheral neuropathy), depression, reduced sex drive
- blurred vision
- jaundice (yellowing of the skin and whites of the eyes)
- liver problems including hepatitis (inflammation of the liver)
- inflammation of the gall bladder, gall stones
- pancreatitis (inflammation of the pancreas)
- skin problems including dermatitis, peeling or itching, red, itchy raised areas of skin
- photosensitivity (a sensitivity to light that can cause skin discolouration or a rash)
- hair loss
- joint or muscle pain, cramp, wasting of the muscles, inflammation of the muscles (myositis), painful arms and legs, temporary paralysis or weakness of the muscles. swelling of the joints
- inflammation of the synovial membrane (synovitis)
- problems getting or maintaining an erection
- acute appendicitis (inflammation of the appendix)
- persistent lack of energy

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gemfibrozil

Keep this medicine out of the sight and reach of children.

Store at or below 25°C.

Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Gemfibrozil contains:

- The active ingredient is gemfibrozil 600 mg
- The other ingredients are pregelatinised maize starch, colloidal anhydrous silica, hydroxypropylcellulose, polysorbate 80, microcrystalline cellulose, calcium stearate, methylhydroxypropylcellulose, macrogol 4000, titanium dioxide (E171) and polydextrose K.

What Gemfibrozil looks like and contents of the pack:

- Gemfibrozil tablets are white to off white, oval-shaped, film-coated tablets. Scored on one side with engraving “93” and “670” on each side of the score line. The other side is plain.
- The tablets are available in pack sizes* of 56, 60, 500 and 1,000 tablets.

*Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder and manufacturer: TEVA UK Limited, Eastbourne, BN22 9AG

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