

## **PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

### **Gemfibrozil 600mg Film-Coated Tablets**

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

- Keep this leaflet. You may need to read it again.
- If you have 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 this medicine 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 this medicine is and what it is used for**

Gemfibrozil belongs to a group of medicines called lipid-lowering medicines or fibrates. These work by helping to reduce cholesterol and triglycerides (fats) in the blood.

Gemfibrozil is used to treat the following:

- To prevent heart disease in men between 40-55 years of age suffering from hyperlipidaemias (where the concentration of fats in the blood is too high) and diet/other appropriate measures have been insufficient to correct the condition
- To prevent heart disease in men with increased cholesterol levels and at high risk for first-time heart problems and statin medicines (HMG-CoA reductase inhibitors) are contraindicated or not well tolerated
- It is also used to treat patients who have high blood cholesterol and triglyceride levels (hyperlipidaemia of types IIa, IIb, III, IV and V), which cannot be controlled by diet or exercise or weight loss or other means alone.

#### **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)
- You suffer from liver disorders
- You suffer from severe kidney disorders
- You suffer from or have a history of suffering from gall bladder or biliary tract disease including gallstones. Treatment with Gemfibrozil should be discontinued if gallstones are found
- You have a history of photoallergy or phototoxicity reactions (allergic reactions caused by exposure to sunlight) during treatment with fibrates
- You are taking repaglinide (a medicine used to reduce blood sugar levels), simvastatin or rosuvastatin (cholesterol-lowering medicines), dasabuvir (used to treat hepatitis C infection) or selexipag (used to treat pulmonary arterial hypertension) (see "Other medicines and Gemfibrozil" section)

##### **Warnings and precautions**

##### **Talk to your doctor before taking Gemfibrozil:**

- If you have an underactive thyroid (hypothyroidism) as this condition must be controlled as much as possible before starting treatment with Gemfibrozil
- If you are diabetic as your condition must be controlled as much as possible before starting treatment with Gemfibrozil
- If you develop muscle pain or tenderness as you should be monitored closely

- If you are at risk of developing a condition in which damaged skeletal muscle tissue breaks down (rhabdomyolysis) due to the following:
  - You suffer from kidney problems
  - You have an underactive thyroid (hypothyroidism)
  - You suffer from alcoholism
  - You are over 70 years of age
  - You or your family have a history of inherited muscular disorders
  - You have a previous history of muscular toxicity (muscle pain or tenderness) with another fibrate or statin (see “Other medicines and Gemfibrozil” section)
- As Gemfibrozil is intended for long-term use, the level of fats in the blood and liver function tests should be performed periodically during treatment. Blood count should be measured every 12 months of treatment with Gemfibrozil. Treatment with Gemfibrozil should be stopped if any abnormalities in the test results persist.

### **Other medicines and Gemfibrozil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

- Anti-diabetic medication, particularly rosiglitazone or repaglinide (used to reduce blood sugar levels) (for repaglinide see “Do not take Gemfibrozil”)
- Dasabuvir, a medicine used to treat hepatitis C infection (see “Do not take Gemfibrozil”)
- Selexipag, a medicine used to treat pulmonary hypertension
- Statins used to lower bad cholesterol and triglycerides, and increase good cholesterol such as atorvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin (for simvastatin see “Do not take Gemfibrozil”)
- Dabrafenib, a treatment for melanoma
- Loperamide, a treatment for diarrhoea
- Montelukast, a treatment for asthma
- Pioglitazone, a treatment used for diabetes
- Warfarin, acenocoumarol, and phenprocoumon (anticoagulants used to thin blood)
- Colestipol resin granules for the treatment of high levels of fat (cholesterol) in your blood
- Bexarotene medication for the treatment of skin cancer
- Colchicine for the treatment of gout
- Paclitaxel, a treatment for cancer
- Enzalutamide, a treatment for prostate cancer

### **Taking Gemfibrozil with food and drink and alcohol**

- Patients should be placed on a diet to help lower their cholesterol levels, which should be continued during treatment with Gemfibrozil.
- Patients should limit their intake of alcohol whilst being treated with Gemfibrozil.
- Gemfibrozil should be taken half an hour before breakfast and/or half an hour before the evening meal.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

#### **Pregnancy**

Do **not** take Gemfibrozil if you are pregnant, trying to become pregnant or think you may be pregnant unless it is absolutely necessary.

#### **Breastfeeding**

Do **not** take Gemfibrozil if you are breast-feeding.

#### **Fertility**

Decreases in male fertility have been observed but this is reversible.

#### **Driving and using machines**

Although unlikely, you may feel dizzy or experience visual disturbances whilst taking this medicine. If either of these symptoms are experienced, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

#### **Gemfibrozil contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### **Gemfibrozil contains sodium**

This medicine contains 36 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.8% of the recommended maximum daily dietary intake of sodium for an adult.

### **3 How to take Gemfibrozil**

**Always take Gemfibrozil exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.**

Before starting treatment with Gemfibrozil, attempts should be made to control fats in the blood:

- With appropriate diet and exercise and weight loss in obese patients
- By stopping smoking
- By limiting intake of alcohol
- Treatment of the causes of secondary hyperlipidaemias such as underactive thyroid (hypothyroidism) and diabetes (see "Warnings and precautions" section)
- These tablets are to be taken orally.
- The score line on the tablet is to facilitate breaking for ease of swallowing and to divide the tablet into equal doses.
- Gemfibrozil should be withdrawn or additional therapy introduced if the therapeutic response is inadequate after three months.

#### **Adults and elderly (over 65 years old)**

- The recommended dose range is 900mg - 1200mg daily.
- A 900mg dose is taken as a single dose (taken as one and a half tablets) half an hour before the evening meal.
- A 1200mg dose is taken as 600mg twice daily, half an hour before breakfast and half an hour before the evening meal.

#### **Patients with kidney disorders**

- Treatment should be started at 900mg daily and kidney function should be assessed before increasing dose.
- Gemfibrozil should **not** be used in patients with severely impaired kidney function (see section 2 "What you need to know before you take Gemfibrozil, Do not take...").

**Gemfibrozil must not be used in patients suffering from liver disorders** (see section 2 "What you need to know before you take Gemfibrozil, Do not take...").

#### **Use in children**

Gemfibrozil Tablets are **not** recommended for children.

#### **If you take more Gemfibrozil than you should**

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **Symptoms of an overdose may include;** stomach cramps, abnormal liver function tests, diarrhoea, increased enzymes in the body (signs of this are muscle pain, tenderness, weakness, swelling, urine becomes dark in colour), joint or muscle pain, feeling or being sick.

#### **If you forget to take Gemfibrozil**

If you forget to take a dose, do not worry. Simply miss that dose and take your next dose at the right time. **Do not take a double dose to make up for a forgotten dose.**

#### **If you stop taking Gemfibrozil**

It is important that you keep taking Gemfibrozil for as long as your doctor has told you to.

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

#### **4 Possible side effects**

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

#### **Seek medical advice immediately if you develop the following symptoms:**

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Swelling of the voice box (laryngeal oedema). Symptoms may include the following:
  - Throat may feel sore, tight, itchy, feel as if there is a “lump” or have difficulty swallowing
  - Voice may become high-pitched, hoarse, develop a full-throated 'barky' cough or be unable to speak
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Muscle weakness or weakness accompanied by dark urine, fever, rapid heart rate or palpitations, nausea or vomiting (rhabdomyolysis)
- Severe abdominal pain, which may indicate you have gallstones (cholelithiasis) or swelling (inflammation) of the gallbladder (cholecystitis)
- Peeling of the skin over large areas of the body (exfoliative dermatitis)
- Abnormal liver function or inflammation of the liver, where signs can include yellowing of the skin or eyes, nausea and abdominal pain

#### **Very common side effects (may affect more than 1 in 10 people)**

- Indigestion (dyspepsia)

#### **Common side effects (may affect up to 1 in 10 people)**

- A sensation of whirling and loss of balance, feeling dizzy or giddy (vertigo)
- Diarrhoea
- Feeling/being sick (nausea/vomiting)
- Constipation
- Feeling bloated/wind (flatulence)
- Rash
- Inflammation of the skin (eczema)
- Headache
- Tiredness, weakness or lack energy (fatigue)

#### **Uncommon side effects (may affect up to 1 in 100 people)**

- Irregular heartbeat (atrial fibrillation)

#### **Rare side effects (may affect up to 1 in 1000 people)**

- Reduction in blood platelets, which increases the risk of bleeding or bruising (thrombocytopenia)
- Looking very pale and feeling very tired (severe anaemia)
- A reduction in white blood cells (leucopenia)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough & rashes due to an increase in certain white blood cells (eosinophilia)
- Insufficient amounts of red blood cells, white blood cells, and platelets (bone marrow failure)
- Changes in blood test results
- Inflammation of the pancreas (pancreatitis)
- Sudden painful swelling (inflammation) of the lower right hand side of the abdomen (acute appendicitis)
- Severe itching (pruritus)
- Skin rash or inflammation (dermatitis)
- Skin rashes with the formation of wheals (urticaria)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Hair loss (alopecia)
- Dizziness
- Sleepiness or drowsiness (somnolence)
- Tingling or numbness in the hands or feet (paraesthesia)

- Disorders of the nervous system e.g. “creeping” sensation and other sensory disorders affecting hands &/or feet (peripheral neuritis/peripheral neuropathy)
- Depression
- Loss of sex drive (decreased libido)
- Inability to have or maintain an erection (erectile dysfunction)
- Blurred vision
- Muscle weakness (myaesthesia/myopathy)
- Painful extremities (arms & legs)
- Muscle pain (myalgia)
- Pain or swelling in the joints (arthralgia/synovitis)
- Inflammation of the muscles (myositis)

### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 to protect the environment.

### **6 Contents of the pack and other information**

#### **What Gemfibrozil contains:**

Each tablet contains 600mg of Gemfibrozil.

**The other ingredients are:** microcrystalline cellulose, maize starch, hydroxypropylcellulose, sodium starch glycollate (type A), polysorbate 80 (tween 80), colloidal anhydrous silica, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide (E171) and macrogol 4000.

#### **What Gemfibrozil looks like and contents of the pack:**

Gemfibrozil are white, oblong, film-coated tablets of 9 x 19mm dimension, with three break marks on both sides.

#### **Gemfibrozil is available in:**

Gemfibrozil Tablets are available in packs of 28, 30, 56 or 100 tablets.

Not all pack sizes may be marketed.

#### **Product Licence Number:**

PL 11311/0099

#### **Marketing Authorisation Holder:**

Tillomed Laboratories Ltd  
 220 Butterfield  
 Great Marlings  
 Luton  
 LU2 8DL  
 United Kingdom

#### **Manufacturer:**

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