

P3207T

Package leaflet: Information for the patient

FENOFRIBRATE 200mg CAPSULES

fenofibrate

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

What is in this leaflet:

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

1. What Fenofibrate is and what it is used for

Fenofibrate belongs to a group of medicines, commonly known as 'fibrates'. These medicines are used to lower the level of fats (lipids) in the blood. For example, the fats known as 'triglycerides'.

Fenofibrate is used, alongside a low-fat diet and other non-medical treatments such as exercise and weight loss, to lower levels of fats in the blood.

Fenofibrate can be used in addition to other medicines (called 'statins') in some circumstances when levels of fats in the blood are not controlled with a statin alone.

Fenofibrate can often also increase the amount of a 'good' type of cholesterol, called HDL or high density lipoprotein cholesterol.

It is always essential to continue a low-fat diet during treatment with Fenofibrate.

2. What you need to know before you take Fenofibrate

Do not take Fenofibrate if:

- You are allergic to fenofibrate or any of the other ingredients of this medicine (listed in Section 6: Contents of the pack and other information)
- While taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light (these medicines include other fibrates and an anti-inflammatory medicine called 'ketoprofen')
- You have severe liver, kidney or gallbladder problems
- You have pancreatitis (an inflamed pancreas which causes abdominal pain), which is not caused by high levels of fat in the blood

Do not take Fenofibrate if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Fenofibrate.

Warnings and Precautions

Talk to your doctor or pharmacist or nurse before taking Fenofibrate if:

- You have any liver or kidney problems.
- You may have an inflamed liver (hepatitis), signs include yellowing of the skin and the whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests)
- You have an under-active thyroid gland (hypo-thyroidism)
- You have diabetes, especially Type 2 diabetes, that is not well controlled
- You have problems with certain proteins in your blood
- You have an alcohol problem
- You are taking other medicines
- You or your family have had muscle problems
- You are over 70 years of age

(Some of the above conditions can lead to high levels of lipids in your blood and need to be corrected before you start therapy with fenofibrate).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Fenofibrate.

Your doctor might want to test your blood or urine to check if Fenofibrate is working properly and also if your kidneys, muscles and liver are working properly.

Effects on muscles

Stop taking Fenofibrate and see a doctor straight away

if you get unexplained cramps or painful, tender or weak muscles while taking this medicine.

- This is because this medicine may cause muscle problems, which may be serious.
- These problems are rare but include muscle inflammation and breakdown. This can cause kidney damage or even death.

Your doctor may do a blood test to check your muscles before and after starting treatment.

The risk of muscle breakdown is higher in some patients.

Tell your doctor if:

- You are over 70 years old
- You have kidney problems
- You have thyroid problems
- You or a close family member has a muscle problem which runs in the family
- You drink large amounts of alcohol
- You are taking medicines called statins to lower cholesterol, such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin
- You have ever had muscle problems during treatment with statins or fibrates, such as fenofibrate, bezafibrate or gemfibrozil

If any of the above apply to you (or you are not sure), talk to your doctor before taking Fenofibrate.

Other medicines and Fenofibrate

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-coagulants to thin your blood (such as warfarin)
- Other medicines to control fat levels in the blood (such as 'statins' or 'fibrates'). Taking a 'statin' at the same time as Fenofibrate may increase the risk of muscle problems
- A particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- Cyclosporin, used to suppress your immune system

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Fenofibrate.

Fenofibrate with food, drink and alcohol

It is important to take the capsule with food, it will not work as well if your stomach is empty.

Pregnancy, breast-feeding and fertility

- Do not take Fenofibrate and tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby
- Do not take Fenofibrate if you are breast-feeding or planning to breast-feed your baby Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine will not affect you being able to drive or use tools or machines.

Fenofibrate Capsules contains sucrose

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

Fenofibrate Capsules contains sodium benzoate

This medicine contains 8.4 micrograms sodium benzoate (E211) in each capsule.

Fenofibrate Capsules contains sodium

This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Fenofibrate

Always take this medicine exactly as your doctor or pharmacist has told you. Also, please read the label on the packet. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

Taking this medicine

- Swallow the capsule whole with a glass of water
- Do not open or chew the capsule
- Take the capsule with food, it will not work as well if your stomach is empty

How much to take

The recommended dose for adults is one capsule of Fenofibrate a day, taken at mealtimes.

Use in children and adolescents

The use of Fenofibrate is not recommended in children under the age of 18.

People with kidney problems

If you have kidney problems, your doctor may tell you to take a lower dose. Ask your doctor or pharmacist about this.

If you take more Fenofibrate than you should

If you take more Fenofibrate than you should or if someone else has taken your medicine, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Fenofibrate

- If you forget a dose, take the next dose with your next meal
- Then take your next capsule at the normal time
- Do not take a double dose to make up for a forgotten dose. If you are worried about this talk to your doctor.

If you stop taking Fenofibrate

Do not stop taking Fenofibrate unless your doctor tells you to, or the capsules make you feel unwell. This is because abnormal levels of fats in the blood need treating for a long period of time.

Remember that as well as taking Fenofibrate it is also important that you:

- Have a low fat diet
- Take regular exercise

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

4. Possible side effects

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

Stop taking Fenofibrate and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- Cramps or painful, tender or weak muscles, these may be signs of muscle inflammation or breakdown, which can cause kidney damage or even death
- Stomach pain, this may be a sign that your pancreas is inflamed (pancreatitis)
- Chest pain and feeling breathless, these may be signs of a blood clot in the lung (pulmonary embolism)
- Pain, redness or swelling in the legs, this may be signs of a blood clot in the leg (deep vein thrombosis)
- Yellowing of the skin and whites of the eyes (jaundice), or an increase in liver enzymes, these may be signs of an inflamed liver (hepatitis)

Stop taking Fenofibrate and see a doctor straight away, if you notice any of the side effects above.

Other side effects include:

Common (affects less than 1 in 10 people):

- Diarrhoea
- Stomach pain
- Wind (flatulence)
- Feeling sick (nausea)
- Being sick (vomiting)
- Raised levels of liver enzymes in the blood, shown in tests
- Increase in homocysteine (too much of this amino acid in the blood has been associated to a higher risk of coronary heart disease, stroke and peripheral vascular disease, although a causal link has not been established)

Uncommon (affects less than 1 in 100 people):

- Headache
- Gallstones
- Reduced sex drive
- Rash, itching or red patches on the skin
- Increase in 'creatinine' produced by the kidneys, shown in tests

- Pancreatitis (inflammation of the pancreas leading to abdominal pain)
- Thromboembolism: pulmonary embolism (blood clot in the lung causing chest pain and breathlessness), deep vein thrombosis (blood clot in the leg causing pain, redness or swelling)
- Muscle pain, muscle inflammation, muscle cramps and weakness

Rare (affects less than 1 in 1,000 people):

- Hair loss
- Increase in 'urea' produced by the kidneys, shown in tests
- Increased sensitivity of your skin to sunlight, sun lamps and sunbeds
- Drop in haemoglobin (that carries oxygen in the blood) and white blood cells - shown in tests.
- Hepatitis (inflammation of the liver), symptoms of which may be mild jaundice (yellowing of the skin and whites of the eyes), stomach pain and itching
- Hypersensitivity (allergic reaction)

Side effect where the chance of it happening are not known

- Severe form of skin rash with reddening, peeling and swelling of the skin that resembles severe burns
- Long-term lung problems
- Muscle breakdown
- Complications of gallbladder stones
- Jaundice
- Feeling dizzy (vertigo)
- Feeling exhausted (fatigue)

If you get any unusual breathing discomfort, tell your doctor straight away.

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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. 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 Fenofibrate

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and the blister 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 Fenofibrate contains

- The active substance is fenofibrate. Each Fenofibrate 200 capsule contains 200 milligrams (mg) of fenofibrate.
- The other ingredients are: sucrose*, maize starch*, povidone K-30*, hypromellose (E 464), sodium lauryl sulfate, dimethicone emulsion 35% (dimethicone, polydimethylsiloxane, polyethylene glycol sorbitan monolaurate, propylene glycol (E 1520), sodium benzoate (E 211), purified water), simethicone emulsion 30% (simethicone, cetyl stearyl alcohol & ethoxylate, sodium benzoate (E 211), purified water) and talc.
- The Composition of Capsule shell is Gelatin, Sodium lauryl sulfate, Titanium dioxide (E171) and Iron Oxide Yellow (E172).

* Sucrose, Maize starch and Povidone K-30 are components of sugar spheres.

What Fenofibrate looks like and contents of the pack

Fenofibrate 200mg capsules are supplied as Size 1 hard gelatin capsules, having yellow cap and clear transparent body, filled with white to off-white spherical pellets.

Dimensions: Approximately 19 mm long and 7 mm wide

Fenofibrate 200mg capsules are provided in blister packs of 10, 28 or 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Crescent Pharma Ltd., Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.



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290 mm

160 mm

Crescent
PHARMA LIMITED

Product:	Fenofibrate 200mg Capsules
Item Code:	P3207T
Size:	160 x 290 mm
Min. Point size:	8pt
O. Artwork	07/02/25
Proof No.	2
Amendment Date:	14/02/25

Colours Used	
	Process Black
	Keyline - Does not print