

290 mm

Package leaflet: Information for the patient
Fenofibrate 160 mg Tablets
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 any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, or pharmacist or nurse.

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.

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
- 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), stomach pain and itching.
- You have an under-active thyroid gland (hypothyroidism).

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

Fenofibrate and effects on muscles
Stop taking Fenofibrate and see a doctor straight away if you get:

- unexplained cramps
- 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.

In particular, 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'). This is because taking a 'statin' in addition to 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.

Pregnancy, breast-feeding and fertility
Tell your doctor if you are pregnant; think you may be pregnant or are planning to have a baby. This is because it is not known how Fenofibrate may affect your unborn baby. You should only use Fenofibrate if your doctor tells you to.

- 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. This is because it is not known whether Fenofibrate passes into human milk.

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

Important information about some of the ingredients of Fenofibrate
This medicine contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine. This medicine contains less than 1 mmol sodium (23 mg) per tablet, 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. 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
Take the tablet with food - it will not work as well if your stomach is empty.

- Swallow the tablet whole with a glass of water.
- Do not crush or chew the tablet.

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

- Have a low fat diet
- Take regular exercise

How much to take
The recommended dose is one tablet a day. If you are already taking one capsule of Lipantil Micro 200mg, you can change to one tablet of Fenofibrate 160 mg. You will still receive the same amount of medicine.

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.

Use in children and adolescents
The use of Fenofibrate is not recommended in children under the

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age of 18.

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

If you forget to take Fenofibrate

- If you forget a dose, take the next dose with your next meal
- Then take your next dose 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 tablets make you feel unwell. This is because you require long-term treatment. If your doctor stops your medicine, do not keep any leftover tablets unless your doctor tells you to.

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:

Uncommon: may affect up to 1 in 100 people

- 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 - these may be signs of a blood clot in the leg (deep vein thrombosis)

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

- allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- 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)

Not known: it is not known how often these happen

- severe skin rash which reddens, peels and swells and looks like a severe burn
- long-term lung problems

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

Other side effects include:

Common: may affect up to 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: may affect up to 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

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

- hair loss
- increase in urea (produced by the kidneys) - shown in tests
- skin is more sensitive to sunlight, sun lamps and sunbeds
- drop in haemoglobin (that carries oxygen in blood) and white blood cells - shown in tests.

Not known: it is not known how often these happen:

- muscle breakdown
- complications of gallbladder stones
- feeling exhausted (fatigue)

Tell your doctor or pharmacist if you notice any of the side effects listed above.

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 website 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. Content of the pack and other information
What Fenofibrate tablets contain

- The active substance is fenofibrate. Each Fenofibrate 160mg tablet contains 160 milligrams (mg) of fenofibrate.
- The other ingredients are: lactose monohydrate, hypromellose, sodium sodium lauryl sulphate, simethicone emulsion, microcrystalline cellulose, croscarmellose sodium and magnesium stearate

What Fenofibrate looks like and contents of the pack
Fenofibrate 160 mg is supplied to you as white to off-white oblong tablets in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer:

Rivopharm UK Ltd.
100 Bishopsgate
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