

FENOFIBRATE 267MG CAPSULES

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.
- 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.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

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

The name of your medicine is Fenofibrate 267mg Capsules (called fenofibrate throughout this leaflet).

This 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.

It is always essential to continue a low-fat diet during treatment with fenofibrate and it is important to exercise.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FENOFIBRATE

Do not take Fenofibrate if:

- You are allergic (hypersensitive) to fenofibrate or any of the other ingredients of this medicine (see Section 6: Contents of the pack and other information)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face throat or tongue
- You have ever had a skin reaction due to sunlight or artificial UV light (such as on a 'sun bed') while taking another fibrate or ketoprofen (anti-inflammatory medicine)
- You have severe kidney problems
- You have severe liver problems including cirrhosis
- You have gallbladder problems
- You have problems with your pancreas (pancreatitis)

Do not take this medicine 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 before taking fenofibrate if:

- You or members of your family suffer from hereditary muscle problems
- 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
- You have liver 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 kidney disease
- You have diabetes, especially Type 2 diabetes, that is not well controlled
- You have problems with certain proteins in your blood
- You have an under-active thyroid gland (hypothyroidism)
- You regularly drink large amounts of alcohol
- You are taking other medicines
- You have low albumin blood levels (hypoalbuminaemia)
- 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 you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking fenofibrate.

Other medicines and fenofibrate

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because fenofibrate can affect the way some other medicines work. Also some medicines can affect the way fenofibrate works.

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

- Any other medicines for high blood fat levels called 'fibrates', such as clofibrate, bezafibrate, or gemfibrozil
- Medicines for thinning the blood (such as warfarin)
- Medicines containing oestrogen such as the contraceptive pill or hormone replacement therapy (HRT)
- Ciclosporin – used following transplant surgery and to treat rheumatoid arthritis
- Pioglitazine – used to treat diabetes

Fenofibrate with food, drink and alcohol

- Fenofibrate should always be taken with food
- Remember to keep your low fat diet while you are taking fenofibrate
- Do not drink large amounts of alcohol while taking fenofibrate, as this can increase the risk of muscle problems

Pregnancy, breast-feeding and fertility

Do not use this medicine if:

- You are pregnant, think you might be pregnant or are planning to have a baby
- You are breast-feeding or planning to breast-feed. This is because small amounts of fenofibrate may pass into the mother's milk

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel dizzy, drowsy or tired while taking fenofibrate. If this happens do not drive or use any tools or machines.

Information about the ingredients of fenofibrate

This medicine contains less than 1 mmol sodium (23 mg) 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. 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 this capsule whole with a glass of water
- Do not open or chew the capsule
- Always take this medicine with food – it will not work as well if your stomach is empty

How much to take

Adults

- The usual dose is one capsule each day

Use in children and adolescents

- Fenofibrate is not recommended for use in children under 18 years old

People with kidney problems

- If you have kidney problems your doctor may prescribe you a lower dose or tell you to wait

longer in between doses

If you take more fenofibrate than you should

If you take more of this medicine than you should, talk to a doctor or go to the nearest hospital casualty department straight away. Take the pack and any remaining capsules with you. This is so the doctors know what you have taken.

If you forget to take fenofibrate

If you forget to take a dose at the right time, take it as soon as you remember with your next meal, then go on as before. Do not take a double dose to make up for a forgotten capsule.

If you are worried about this talk to your doctor.

Blood tests

- During treatment with fenofibrate your doctor may do blood tests to check how your liver and kidneys are working or check whether you might be particularly at risk of getting muscle problems.
- If you are going to have any other blood tests, it is important to tell the person doing the test that you are taking fenofibrate. This is because fenofibrate can affect the result of some blood tests.

If you stop taking fenofibrate

Do not stop taking fenofibrate unless your doctor tell you to, or the capsules make you feel unwell. This is because abnormal levels of fat 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.

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 or go to a hospital straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

Uncommon (affects less than 1 in 100 people):

- You suddenly get pain in your head or chest or begin to have any breathing difficulties. These could 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)
- You get severe stomach pain which may reach through to your back. This could be a sign of pancreatitis

Rare (affects less than 1 in 1000 people):

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to fenofibrate
- You get unexplained pain, tenderness or weakness in the muscles or pain in your joints. You may also have a high temperature or tiredness. This could be a rare, but possibly life-threatening illness called rhabdomyolysis
- You get symptoms such as yellowing of the skin and white of the eyes (jaundice), tiredness or fever or an increase in liver enzymes. These may be signs of an inflamed liver (hepatitis)

Not known (frequency cannot be estimated from the available data):

- Severe form of skin rash with reddening, peeling and swelling of the skin that resembles severe burns

Other side effects include:

Common (affects less than 1 in 10 people):

- Feeling sick (nausea) or being sick (vomiting), diarrhoea, wind (flatulence), indigestion or stomach pains
- Fenofibrate can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly
- 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
- Skin rash (which may be itchy or lumpy)
- Muscle pain, muscle inflammation, muscle cramps and weakness
- Problems with your sex drive
- Increase in 'creatinine' produced by the kidneys – shown in tests
- Pain below your ribs on the right side or in your right shoulder, feeling sick or being sick, (particularly after eating following a fatty meal). This may mean you have gallstones

Rare (affects less than 1 in 1000 people):

- Being more sensitive to the sun than usual.

In some cases this may cause lumps or boils to appear on your skin. This side effect can also happen after using a sun lamp (UV)

- Hair loss (alopecia)
- Increase in urea produced by the kidneys – shown in tests
- Feeling tired, faint or dizzy, shortness of breath, pale skin. These could be signs of anaemia
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia) – shown in tests

Not known (frequency cannot be estimated from the available data):

- Balance problems, feeling dizzy, possibly with a feeling of spinning (vertigo)
- Feeling short of breath, especially during or after exercise, and a dry cough
- Tiredness (fatigue)
- Long-term lung problems
- Complications of gallbladder stones

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

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 internet 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.
- Do not use this medicine after the expiry date which is stated on the carton. 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 267mg Capsules contain

Each capsule contains 267mg of fenofibrate as the active substance.

The other ingredients are, lauroyl macroglycerides, macrogol, hydroxypropylcellulose, and sodium starch, glycolate, gelatin, red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172), titanium dioxide (E171) and indigo carmine (E132).

What fenofibrate looks like and contents of the pack

Fenofibrate capsules are green and caramel hard gelatin capsules. They are supplied in blister packs of 28 capsules.

The Marketing Authorisation Holder is:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

The Manufacturer is:

Zentiva Pharma UK Limited,
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