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Package leaflet: Information for the patient

Fenofibrate 67mg 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 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 Fenofibrate capsules are and what they are used for
2 What you need to know before you take Fenofibrate capsules
3 How to take Fenofibrate capsules
4 Possible side effects
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1 What Fenofibrate capsules are and what they are used for

Fenofibrate capsules belong 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 capsules are 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 capsules 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 capsules

Do not take Fenofibrate capsules if:

- you are **allergic** to fenofibrate or any of the other ingredients of this medicine (listed in section 6)
- 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 capsules if any of the above apply to you.
If you are not sure, talk to your doctor or pharmacist before taking Fenofibrate capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fenofibrate capsules if you:

- have any **liver** or **kidney** problems
- may have an inflamed **liver** (hepatitis) – signs include yellowing of the skin and whites of the eyes (jaundice) and an increase in **liver enzymes** (shown in blood tests)
- have an under-active **thyroid gland** (hypo-thyroidism)

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- have **diabetes**, especially Type 2 diabetes, that is not well controlled
- have problems with certain **proteins in your blood**
- have an **alcohol** problem
- are taking **other medicines**
- or your family have had **muscle problems**
- 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 capsules.
Your doctor might want to test your blood or urine to check if Fenofibrate capsules are working properly and also if your kidneys, muscles and liver are working properly.

Effects on muscles

Stop taking Fenofibrate capsules 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
- have **kidney** problems
- have **thyroid** problems
- or a close family member has a **muscle problem** which runs in the family
- drink large amounts of **alcohol**
- are taking medicines called **statins** to lower cholesterol – such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin
- 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 capsules.

Other medicines and Fenofibrate capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 capsules may increase the risk of muscle problems
- A particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)
- Ciclosporin - 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 capsules.

Fenofibrate capsules 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.

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Pregnancy, breast-feeding and fertility
- Do not take Fenofibrate capsules and tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby
- Do not take Fenofibrate capsules 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 contain lactose
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 contain sunset yellow (E110)
May cause allergic reactions.

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

3 How to take Fenofibrate capsules
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.
Swallow the capsules **whole with water during a meal.**

Taking this medicine
Adults (including the elderly)
Three capsules a day, taken in divided doses. Your doctor will monitor your response to the treatment.

Use in children and adolescents
One capsule a day per 20kg of bodyweight.

People with kidney problems
If you have impaired kidney function, your doctor may prescribe you a lower dose.

If you take more Fenofibrate capsules than you should
If you (or someone else) swallow a lot of capsules at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take Fenofibrate capsules
- If you forget a dose, take the next dose with your next meal
- Then take the 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 capsules
Do not stop taking Fenofibrate capsules 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 capsules it is important that you:
- Have a low fat diet
- Take regular exercise.

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.
Stop taking Fenofibrate capsules and see a doctor immediately, 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):
- **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)
- **Stomach pain** - this may be a sign that your pancreas is inflamed (pancreatitis).

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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 (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 - these may be signs of severe skin reactions (e.g erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- **Cramps or painful, tender or weak muscles** - these may be signs of muscle inflammation or breakdown, which can cause kidney damage or even death.

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; muscle pain; muscle inflammation; muscle cramps and weakness.

Rare (may affect up to 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; stomach pain and itching.

Not known (frequency cannot be estimated from the available data):
Long-term lung problems; complications of gallbladder stones; feeling dizzy (vertigo); feeling exhausted (fatigue).

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 capsules
Keep this medicine out of the sight and reach of children.
Do not store above 25°C.
Store in the original package.
Do not take this medicine after the expiry date which is stated on the label/carton/bottle. 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 Fenofibrate capsules contain
- The active substance (the ingredient that makes the capsules work) is micronised fenofibrate. Each capsule contains 67mg of the active substance.
- The other ingredients are lactose monohydrate, pregelatinised starch, sodium lauryl sulfate, povidone, magnesium stearate, gelatin, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110).

What Fenofibrate capsules look like and contents of the pack
Fenofibrate capsules are yellow, hard, gelatine capsules.
Pack size is 90.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstaple, EX32 8NS, UK.

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If you would like a leaflet with larger text, please contact 01271 385257.

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