Fenofibrate 67mg capsules

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

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
4. 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
5. How to store Fenofibrate capsules
6. Contents of the pack and other information

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 (statins) in some circumstances when levels of fats in the blood are not controlled with a statin alone.

What you need to know before you take Fenofibrate capsules

Do not take Fenofibrate capsules and tell your doctor if you:
1. are allergic to fenofibrate or any of the other ingredients in the capsules (see section 6).
2. have developed a sensitivity to sunlight or artificial light (e.g. sunbeds) when taking fibrates (e.g. fenofibrate or bezafibrate) or ketoprofen (used for muscle and bone disorders, gout or period pain).
3. have severely impaired liver function.
4. have severe kidney problems.
5. have problems with your pancreas.
6. have gall bladder or liver disease.

Other medicines and Fenofibrate capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially:
1. oral anti-coagulants e.g. warfarin (used to prevent blood clotting).
2. statins e.g. atorvastatin (used to lower cholesterol).
3. ciclosporin (used to suppress the immune system).
4. phenylbutazone (a non-steroidal anti-inflammatory drug).
5. other fibrates e.g. bezafibrate (used to lower cholesterol and other fats (lipids) in the blood).
6. oestrogen or medicines which contain oestrogen (contraceptives).

Pregnancy and breast-feeding

Fenofibrate capsules should not be used if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Fenofibrate capsules contain lactose

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fenofibrate capsules if you:
1. have or have had impaired kidney function.
2. have kidney disease.
3. have severely increased levels of a type of fat (triglycerides) in the blood (severe hypertriglyceridaemia) (seen in a blood test).
4. have any of the following which may increase the risk of you developing abnormal muscle breakdown:
   - impaired kidney function
   - an underactive thyroid
   - a high alcohol intake
   - are over 70 years old
   - have had or have a family member with a history of hereditary muscular disorders.
5. have decreased levels of a certain protein in the blood (hypoaalbuminaemia) (seen in a blood test).
6. are already taking a fibrate (e.g. bezafibrate) or a statin (e.g. atorvastatin), especially if you have muscle disease.
7. have poorly controlled diabetes mellitus (type II).
8. have nephrotic syndrome characterised by large amounts of protein in the urine, water retention and increased levels of fats in the blood.
9. have a condition which effects the amount of protein in the blood (dysproteinemia).
10. have obstructive liver disease.
11. are taking medicines which may effect fat metabolism (e.g. thiazides, beta blockers, corticosteroids or antiretrovirals).

Fenofibrate Capsules
67mg x 90’s (UK)

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Ingredient warning
Fenofibrate capsules contain sunset yellow (E110) which may cause allergic reactions.

Tests
Your doctor may want to carry out tests to monitor the levels of certain enzymes within your body.

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.

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

Children
One capsule a day per 20kg of bodyweight.

Impaired kidney function
If you have impaired kidney function, your doctor may prescribe you a lower dose.

If you take more 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 the capsules
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

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

Stop taking Fenofibrate capsules and tell your doctor immediately if you develop:
• Muscle poisoning: muscle pain, breakdown, inflammation, cramps or weakness, increase in the levels of a certain enzyme within the body (seen in a blood test).

Contact your doctor immediately if you develop:
• An allergic reaction: swelling of the face, lips, tongue or throat, itchy skin rash, narrowing of the airways causing difficulty breathing or swallowing.
• Hepatic: yellowing of the skin or whites of the eyes (jaundice), itching.
• Common (may affect up to 1 in 10 people):
  Headache, tiredness, spinning sensation, stomach or intestine disorders such as feeling or being sick, stomach pains, diarrhoea and wind. Skin rash, itching, a skin rash with pale or red irregular raised patches with severe itching, sensitivity to sunlight or artificial light (e.g. sun beds) which may include reddening of the skin, blisters or lumps.
• Uncommon (may affect up to 1 in 100 people):
  Increased levels of a certain enzyme within the body (seen in a test), muscle toxicity (muscle pain, inflammation, cramps and weakness), blood clotting, inflammation of the pancreas causing stomach and back pain.

If you notice any of the following side effects or notice any other effects not listed:

Common (may affect up to 1 in 10 people):
• Liver disease (interstitial pneumopathies), inflammation of the liver (hepatitis) causing yellowing of the skin or whites of the eyes (jaundice) or tiredness, development of gallstones, abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis).

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
By reporting side effects you can help provide more information on the safety of this medicine.

How to store Fenofibrate capsules
Keep this medicine out of the sight and reach of children.

Store in the original package.
Do not use Fenofibrate capsules after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

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
Actavis, 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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