

## **Package leaflet: Information for the patient**

### **Fenofibrate 200 mg Capsules**

### **Fenofibrate 267 mg 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, 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, 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 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

#### **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.

Fenofibrate Capsules 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 Capsules.

#### **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). An allergic reaction can include rashes, hives, itching, swelling of face/lips/hands/feet or breathing difficulties
- 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 drug 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 kidney problems (your doctor may need to start you on a lower dose)
- if you have any liver problems. You may have an inflamed liver – signs include yellowing of the skin and whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests)
- if you have an under active thyroid gland (hypo-thyroidism)
- if you have diabetes, especially Type 2 diabetes, that is not well controlled
- if you have problems with certain proteins in your blood
- if you have an alcohol problem
- if you are taking other medicines
- if you or your family have had muscle problems
- if 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 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 which can cause kidney damage or even death.

Your doctor may do a blood test to check the condition of 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 have 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 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.

**You should avoid drinking alcohol with Fenofibrate Capsules as this increases the risk of muscle problems.**

#### **Pregnancy, breast-feeding and fertility**

Do not take Fenofibrate Capsules and tell your doctor if you are pregnant, think you may 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 your ability to drive, use tools or use machines.

#### **Fenofibrate Capsules contain lactose**

This medicine contains 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)**

This medicine also contains sunset yellow (E110) which is found in the 200 mg capsules. This is a colouring agent and may cause an allergic reaction.

### **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 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.

The recommended dose for adults is one capsule of Fenofibrate 200 mg a day, taken at mealtimes. However your doctor may want you to take one capsule of Fenofibrate 267 mg a day (higher dose).

#### **Use in children and adolescents**

The use of Fenofibrate Capsules are 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 Capsules than you should**

If you take more Fenofibrate Capsules than you should, contact your doctor or go to the nearest hospital casualty department immediately. Take this leaflet or some capsules with you so your doctor will know what you have taken.

### **If you forget to take Fenofibrate Capsules**

- 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 Capsules**

Do not stop taking this medicine 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 also 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.

### **Serious side effects:**

**Stop taking Fenofibrate Capsules and see a doctor immediately or go to the casualty department at your nearest hospital 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 your leg– these 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 Capsules and see a doctor straight away if you notice any of the side effects above

### **Other side effects**

#### 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 with 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
- 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: may affect up to 1 in 10,000 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) – signs may include swelling of the face/lips/tongue or throat which may cause difficulty in breathing.

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
- Long-term lung problems
- Muscle breakdown
- Complications with gallbladder stones
- Jaundice
- Feeling exhausted (fatigue)
- Feeling dizzy (vertigo)

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

If you get any side effects, talk to your doctor, 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 or pharmacist. 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](http://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 use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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**

- Each capsule contains 200 mg or 267 mg of the active substance micronised fenofibrate.
- The other ingredients are sodium lauryl sulphate, lactose, pregelatinised starch, crospovidone, talc, colloidal anhydrous silica, magnesium stearate, gelatin and titanium dioxide (E171).
- The black printing ink contains shellac glaze, iron oxide black (E172) and propylene glycol.
- The 200 mg capsules also contains sunset yellow FCF (E110).
- The 267 mg capsules also contain FD & C blue No. 2 (E132) and yellow iron oxide (E172).

### **What Fenofibrate Capsules look like and contents of the pack**

Fenofibrate Capsules are available in pack sizes of 10, 14, 20, 28, 30, 56, 60 and 90 capsules.  
Not all pack sizes may be marketed.

Fenofibrate 200 mg Capsules are orange cap/orange body imprinted with 'FB200' on cap and body containing white to off-white granular powder.

Fenofibrate 267 mg Capsules are ivory yellow cap/green body imprinted with 'FB267' on cap and body containing white to off-white granular powder.

### **Marketing Authorisation Holder**

SUN PHARMA UK LIMITED

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