

Fenofibrate Tablets USP 160mg/200mg Taj Pharma

Package leaflet: Information for the user (Fenofibrate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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.

In this leaflet:

1. What Fenofibrate Tablets are and what they are used for
2. Before you take Fenofibrate Tablets
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4. Possible side-effects
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1. What Fenofibrate Tablets are and What they are used for

The name of your medicine is Fenofibrate 160mg Tablets (hereafter referred to as Fenofibrate Tablets). Fenofibrate Tablets 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 Tablets 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 Tablets 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.

2. Before you take Fenofibrate Tablets

Do not take Fenofibrate Tablets:

- if you are allergic to fenofibrate or any of the other ingredients of Fenofibrate Tablets
- if you have a liver disorder
- if you have a kidney disorder or severe kidney problems
- if you have known allergic reactions to light during treatment with fenofibrate or ketoprofen (an anti-inflammatory drug)
- if you have gallbladder disease
- if you have inflammation of the pancreas. Fenofibrate Tablets must not be used in children.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Fenofibrate Tablets if:

- you or somebody in your family has had muscular disorders
- you have thyroid problems
- you have kidney disease
- you drink a lot of alcohol.

You will have liver function tests before treatment and also at regular intervals during the first year of treatment. Your kidney function may also be checked by laboratory tests at the beginning of your treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Take care when using any of the following medicines:

- blood thinners (anticoagulants) – an increased risk of bleeding can occur when fenofibrate is taken with these medicines
- ciclosporin – patients can encounter reversible kidney problems when fenofibrate is taken with ciclosporin
- statins or other ‘fibrate’ medicines – an increased chance of muscular disorders

exists when fenofibrate is taken with statins or other ‘fibrate’ medicines

- contraceptives – oestrogen-containing contraceptives may interfere with the effects of fenofibrate.

Pregnancy and breast-feeding

The use of this medicine is not recommended in pregnant women as there is not sufficient experience of use during pregnancy. If you become pregnant during the treatment, you should stop taking the medicine and contact your doctor.

This medicine should not be used whilst breast-feeding as it is not known whether the medicine is excreted in breast milk.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Fenofibrate Tablets will not affect your ability to drive or operate machinery. **Important**

information about some of the ingredients of Fenofibrate Tablets

This medicinal product contains **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Fenofibrate Tablets

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.

You should continue on a low fat diet. **Adults and the elderly**

The usual dose is one tablet daily. The tablet should be swallowed whole together with a meal.

In addition to the diet, this medicine should be continued long-term and monitored regularly.

To use this medicine appropriately, it is essential to undergo regular medical check-ups.

Children and adolescents under 18 years

Children and adolescents under 18 years should **not** be given Fenofibrate Tablets.

If you have the impression that the effect of Fenofibrate Tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more Fenofibrate Tablets than you should

If anyone has taken an overdose of Fenofibrate Tablets (that is more than the doctor has prescribed), seek medical help immediately, either by calling a doctor or going to the nearest hospital casualty department. Always take the labelled medicine container with you, even if there are no tablets left.

If you forget to take Fenofibrate Tablets

Do not take a double dose to make up for a

forgotten tablet. If you forget to take a dose, don't worry; just take your next tablet when it is due.

4. Possible side-effects

Like all medicines, Fenofibrate Tablets can have side-effects, although not everyone gets them. You should contact your doctor if you experience severe or troublesome symptoms.

Tell your doctor immediately if you experience any of the following rare side-effects:

- muscle pain, muscle cramps or muscle weakness - (symptom(s) of rhabdomyolysis, abnormal muscle breakdown which can lead to kidney problems)
- yellowing of the skin or itching - (symptom(s) of hepatitis or liver disease).

Common side-effects (occurring in more than 1 in 100 patients) include:

- stomach pain
- nausea
- vomiting
- diarrhea

- flatulence

Uncommon side-effects (occurring in more than 1 in 1,000 patients) include:

- rash
- itching
- urticaria (hives)
- gallstones
- inflammation of the pancreas
- blood clots in the leg causing redness or swelling (deep vein thrombosis)
- sensitivity to light.

Rare side-effects (occurring in more than 1 in 10,000 patients) include:

- hair loss
- muscle pain
- muscle inflammation
- muscle cramps
- muscle weakness

Very rare side-effects (occurring in less than 1 in 10,000 patients) include:

Hepatitis, skin reactions to light leading to redness, blisters, or swelling. This can occur any time after starting the medicine.

Not Known – frequency cannot be determined from the available data

- rhabdomyolysis
- lung disease.

Fenofibrate can also affect the results of laboratory tests.

These include:

Common: mild changes in liver enzymes

Uncommon: changes in kidney function tests

Rare: decreased levels of blood haemoglobin and white blood cells.

If any of the side-effects get serious or if you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

5. How to store Fenofibrate Tablets

Keep out of the sight and reach of children. No special precautions for storage.

Do not use Fenofibrate Tablets after the expiry date which is stated on the blister/carton. 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.

6. Further Information

What Fenofibrate Tablets contains

The active substance is fenofibrate.

a) Each film coated tablet contains:

Fenofibrate USP	160mg
Excipients	q.s.

b) Each film coated tablet contains:

Fenofibrate USP	160mg
Excipients	q.s.

The other ingredients are sodium laurilsulphate, lactose monohydrate, hypromellose, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

What Fenofibrate Tablets look like and contents of the pack

Fenofibrate Tablets are white or off-white oblong.

Blister strips (PVC/PVDC – Aluminium).

Boxes of 7, 14, 28, 30, 50, 90, 100 and 500 tablets.

Not all pack sizes may be marketed.

7. Manufactured In India By:

TAJ PHARMACEUTICALS LTD.

Mumbai, India



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