

APO-Fenofibrate

fenofibrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

APO-Fenofibrate contains the active ingredient fenofibrate.

Fenofibrate is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood.

Fenofibrate belongs to a group of medicines known as fibric acid derivatives. It works through the activation of a cell nuclear receptor called PPAR α , which reduces the amount of triglycerides and bad cholesterol made in the body and increases the good cholesterol.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol becomes too high.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed.

Over time, this can form hard areas (called plaque) on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack and angina), and stroke.

Cholesterol is carried through the body by different proteins, LDL and HDL. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

In most patients, fenofibrate reduces the bad cholesterol and can actually raise the good cholesterol. It does not reduce the cholesterol that comes from fat in food.

Therefore, when you are taking APO-Fenofibrate, you also need to follow a low-fat diet and other measures, such as exercise and weight control.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine only available with a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing fenofibrate
- any fibrates (such as gemfibrozil)
- ketoprofen
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

Fenofibrate passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have any of the following medical conditions:

- liver disease
- severe kidney disease
- allergic reactions to sunlight or UV light (photoallergy) during treatment with fibrates or ketoprofen
- are currently taking another fibrate drug (e.g. gemfibrozil)
- disease of the gallbladder or pancreas (except if it is due to

high blood levels of a type of fat called triglycerides)

- muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- an intolerance to some sugars.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- muscular aching, tenderness or weakness not caused by exercise

The risk of muscle breakdown is higher in some patients. Tell your doctor if you:

- are over 70 years old
- have kidney problems
- have decreased levels of a certain protein in the blood (hypoalbuminaemia)
- have an underactive thyroid
- have muscle problems 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, vitamins or supplements, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and fenofibrate may interfere with each other. These include:

- oral anti-coagulants, medicines used to prevent blood clots
- other cholesterol regulating medicines including statins (e.g. pravastatin, atorvastatin and simvastatin) and fibrates
- ciclosporin, a medicine which suppresses the immune system
- glitazones, used to reduce sugar levels
- phenylbutazone, used to treat pain and inflammation)
- oral hormonal contraceptives containing estrogen/ethinyl estradiol and norethindrone (birth control pills)
- thiazides, also known as fluid or water tablets
- beta blockers (e.g. atenolol, carvedilol, timolol or metoprolol), used to treat high blood pressure, heart conditions, glaucoma and migraine

These medicines may be affected by fenofibrate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

The initial recommended dose is 145 mg daily, taken as 1 x 145 mg tablet.

Your doctor may prescribe a lower dose if you have kidney problems.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

Fenofibrate helps to regulate your levels of cholesterol (both LDL and HDL) and triglycerides but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include diarrhoea and nausea.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. These may include cholesterol and other blood tests.

Reduce your saturated fat intake and eat plenty of fruit and vegetables.

Doing this will help control your cholesterol (and triglyceride) levels, as well as your weight.

Be active by maintaining an exercise program that your doctor or other health professional recommends.

This will also help control your cholesterol levels and weight.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Fenofibrate may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

Tell your doctor if you drink alcohol. Drinking large quantities of alcohol may increase your chance of fenofibrate causing liver problems.

Things that would be helpful for reducing the chance of coronary heart disease

Lowering high cholesterol can help reduce your chances of having Coronary Heart Disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause.

Some self-help measures suggested below may help your condition and help reduce your chances of having CHD:

- Diet - continue the healthy diet recommended by your doctor, dietitian or pharmacist.
- Weight - your doctor may advise you to lose weight if you are overweight.
- Exercise - make exercise a part of your routine - walking is good. Ask your doctor for advice before starting exercise.
- Smoking - your doctor will advise you to stop smoking.

Talk to your doctor, pharmacist, or dietitian about these measures and for more information.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

Fenofibrate helps most people with high cholesterol, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach pain or discomfort
- back pain
- muscular pain or spasms
- headache
- unusual tiredness or weakness
- diarrhoea or constipation
- nausea or vomiting
- skin reactions, photosensitivity reactions
- sore throat and discomfort when swallowing (pharyngitis)
- runny or blocked nose, sneezing, facial pressure or pain (rhinitis)
- sexual dysfunction

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson Syndrome)
- painful red areas, then large blisters and ends with peeling of layers of skin – this is accompanied by fever and chills, aching muscles and generally feeling unwell (toxic epidermal necrolysis)
- red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. You may have fever, sore throat, headache and/or diarrhoea (erythema multiforme)
- difficulty in breathing
- severe abdominal pain
- chest pain

- temporary paralysis of the muscles or muscle pain/tenderness
- yellowing of the skin and eyes and dark coloured urine
- blood clot in the leg causing pain, redness or swelling (deep vein thrombosis)
- little or no urine passed, drowsiness, nausea, vomiting, breathlessness, confusion
- fever, shivering, weight loss
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does tests from time to time to check your progress. This includes:

- increase in serum/blood creatinine, increase in creatinine phosphokinase, increase in blood urea.
- decrease in haemoglobin and haematocrit, decrease in white blood cell (including leukocytes), decrease in platelets (a type of blood cells which help in blood clotting)
- decrease in HDL-cholesterol levels
- abnormality/increase in liver enzymes/liver function [elevated levels of serum transaminases (ALT and AST)]

Storage and Disposal

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

APO-Fenofibrate 48 mg tablets

White to off-white biconvex oblong tablets, ca 10.5 x 5.8 mm, debossed with "F" on one side and "48" on the other side. AUST R 291653.

Available in boxes of 60 tablets.

APO-Fenofibrate 145 mg tablets

White to off-white biconvex oblong tablets, ca 15.5 x 8.5 mm, debossed with "F" on one side and "145" on the other side. AUST R 291652.

Available in boxes of 30 tablets.

Ingredients

This medicine contains 48 or 145 mg of fenofibrate as the active ingredient.

This medicine also contains the following:

- hypromellose
- sodium lauryl sulfate
- lactose
- croscarmellose sodium
- simethicone emulsion 30%
- magnesium stearate

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Distributor

This medicine is distributed in Australia by:

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

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