

FENOFIBRATE SANDOZ®

fenofibrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fenofibrate Sandoz.

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 or pharmacist 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 Fenofibrate Sandoz is used for

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

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 Sandoz reduces the bad cholesterol and can actually raise the good cholesterol.

Patients with type 2 diabetes may have some level of diabetic retinopathy, a complication of diabetes that may lead to vision loss or impairment. Fenofibrate Sandoz has been shown to slow the progression of diabetic retinopathy in patients diagnosed with this condition.

Fenofibrate Sandoz does not reduce the cholesterol that comes from fat in food.

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

How Fenofibrate Sandoz works

Fenofibrate 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.

Fenofibrate Sandoz belongs to a group of medicines known as fibric acid derivatives.

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 purpose.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Fenofibrate Sandoz

When you must not take it

Do not take Fenofibrate Sandoz 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 symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take this medicine if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

The active ingredient in Fenofibrate Sandoz passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have:

- liver disease
- severe kidney disease
- disease of the gallbladder or pancreas
- experienced muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

Do not take this medicine if you are taking another fibrate.

Do not take this medicine if you are allergic to peanuts, peanut oil, soy lecithin or related products.

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

Safety and effectiveness of Fenofibrate Sandoz in children has not been established.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

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

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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you take Fenofibrate Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with each other. These include:

- oral anti-coagulants (medicines used to prevent blood clots)
- other cholesterol regulating medicines including fibrates
- ciclosporin (a medicine which suppresses the immune system)
- glitazones (medicines to reduce sugar levels).

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

Your doctor has more information on medicines to be careful with or to avoid while taking Fenofibrate Sandoz.

How to take Fenofibrate Sandoz

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 instructions on the box, 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 tablet(s) whole with a full glass of water.

When to take it

Fenofibrate Sandoz can be taken at any time of the day, with or without food. Any dietary measures started

before treatment with Fenofibrate Sandoz should be continued.

Take Fenofibrate Sandoz 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.

How long to take it

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

Fenofibrate Sandoz helps to regulate your levels of cholesterol (both LDL and HDL) and triglycerides. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor if you expect to keep your levels controlled. If you stop taking Fenofibrate Sandoz, your levels may become abnormal again.

If you forget to take it

If it is almost time for 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 advice

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fenofibrate Sandoz. 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
- nausea.

While you are using Fenofibrate Sandoz

Things you must do

Have your blood fats checked when requested by your doctor to make sure Fenofibrate Sandoz is working.

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

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 that you are taking this medicine.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not stop taking Fenofibrate Sandoz, or change the dosage,

without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Fenofibrate Sandoz affects you.

This medicine may cause dizziness in some people.

Avoid drinking large quantities of alcohol while you are taking this medicine.

Drinking large quantities of alcohol may increase your chance of Fenofibrate Sandoz causing liver problems.

Things that may help you reduce 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. Talk to your doctor, pharmacist, or dietician about these measures and for more information.

- Diet - continue the low fat diet recommended by your doctor, dietician 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.

Side effects

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

It helps most people with high cholesterol, but it may have unwanted side effects in a few people. All medicines have some unwanted side effects. Sometimes they are serious, but 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 this list of possible 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
- headache
- muscular pain or spasms
- unusual tiredness or weakness
- diarrhoea or constipation
- nausea
- skin reactions, photosensitivity reactions
- 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:

- difficulty in breathing
- severe abdominal pain
- chest pain
- temporary paralysis of the muscles
- yellowing of the skin and eyes and dark coloured urine

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

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

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

After using Fenofibrate Sandoz

Storage

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

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it 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 medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Fenofibrate 145 mg - White to off white, oval, biconvex film coated tablets, debossed with J on one side and 136 on the other side.

The 145 mg strength is available in blister packs of 30 tablets

Ingredients

Fenofibrate contains 145 mg of fenofibrate as the active ingredient:

The tablets also contain the following inactive ingredients:

- sucrose
- hypromellose
- sodium lauryl sulfate
- lactose monohydrate
- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate
- Opadry AMB complete film coating system 80W68912 white (PI 12258).

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

® = Registered Trademark

This leaflet was prepared in July 2020.

Australian Registration Number(s)
145 mg tablets: AUST R 280720