

Fenofibrate Mylan™

fenofibrate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Fenofibrate Mylan.

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 Mylan is used for

Fenofibrate Mylan 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 Mylan reduces the bad cholesterol and can actually raise the good cholesterol.

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

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

How Fenofibrate Mylan works

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

Ask your doctor if you have any questions about why it 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 Mylan

When you must not take it

Do not take Fenofibrate Mylan 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 breastfeed if you are taking this medicine.

The active ingredient in Fenofibrate Mylan passes into breast milk and there is a possibility 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 product.

Do not give Fenofibrate Mylan to anyone under the age of 18 years.

The safety and effectiveness of Fenofibrate Mylan 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 any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist 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, intend to become pregnant or are breastfeeding.

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 Mylan.

Taking other medicines

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

Some medicines may interfere with each other. These include:

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

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

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

How to take Fenofibrate Mylan

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 Mylan can be taken at any time of the day, with or without food. Any dietary measures started before treatment with Fenofibrate Mylan should be continued.

Take Fenofibrate Mylan 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 Mylan 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 Mylan, 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 getting an unwanted side effect.

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

If you have trouble remembering when 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 New Zealand 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Fenofibrate Mylan. 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 Mylan

Things you must do

Keep all of your doctor's appointments. Your doctor may want to check your blood cholesterol and other blood tests to check your progress. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fenofibrate Mylan.

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 Mylan, 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 Mylan 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 Mylan 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 dietitian about these measures and for more information.

- 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.

Side effects

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

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
- muscular pain or spasms
- headache
- 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
- muscle pain, tenderness or weakness not caused by exercise
- 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 Mylan

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 or pharmacist 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 Mylan comes in two types of tablets:

Fenofibrate Mylan 48 mg - yellow, oval, film-coated tablet engraved with "FI" on one side.

Fenofibrate Mylan 145 mg - white, oblong, film-coated tablet engraved "145" on one side and "Fournier logo" on the reverse.

The 48 mg strength is available in boxes of 60 tablets.

The 145 mg strength is available in boxes of 30 tablets.

Ingredients

Fenofibrate Mylan contains either 48 mg or 145 mg of fenofibrate as the active ingredient.

The tablets also contain the following inactive ingredients:

- sucrose
- hypromellose
- sodium lauryl sulfate
- lactose monohydrate
- crospovidone
- microcrystalline cellulose
- colloidal anhydrous silica
- docusate sodium
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- purified talc
- lecithin
- xanthan gum

In addition to the ingredients listed above the 48 mg tablet also contains:

- indigo carmine aluminium lake
- quinoline yellow aluminium lake
- sunset yellow FCF aluminium lake

Supplier

Fenofibrate Mylan is made in Ireland.

Fenofibrate Mylan is supplied in Australia by:

Mylan Health Pty Ltd
Level 1, 30 The Bond,
30-34 Hickson Road
Millers Point, NSW 2000
Australia

www.mylan.com.au

Phone: 1800 314 527

™ Trademark

This leaflet was prepared in June 2019.

Australian Registration Number(s)

48 mg tablets: AUST R 230444

145 mg tablets: AUST R 230443

Version No. 4