

Fenofibrate RBX®

fenofibrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fenofibrate RBX.

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 RBX is used for

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

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body for many things, such as making bile acids (which help digest food) and some hormones.

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.

Having high levels of 'bad' cholesterol and triglycerides can be a problem. 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 RBX reduces the bad cholesterol and can actually raise the good cholesterol.

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

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

How Fenofibrate RBX works

Fenofibrate RBX 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 RBX 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 RBX

When you must not take it

Do not take Fenofibrate RBX if you have an allergy to:

- any medicine containing fenofibrate
- any medicine containing gemfibrozil
- 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:

- have liver disease
- experience allergic reaction to sunlight or UV light (photoallergy) during treatment with fibrates or ketoprofen
- are currently taking another fibrate drug (e.g., gemfibrozil etc)
- have severe kidney disease
- have disease of the gallbladder or pancreas except if it is due to high blood levels of a type of fat called triglycerides
- have experienced muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.

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

The safety and effectiveness of Fenofibrate RBX in children has not been established.

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.

It is not known whether the active ingredient in Fenofibrate RBX passes into breast milk. Fenofibrate RBX should not be administered to breastfeeding women.

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.

Do not take it if you have been told by your doctor that you have an intolerance to some sugars.

Contact your doctor before taking this medicinal product.

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.

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 decreased levels of a certain protein in the blood (hypoalbuminaemia) (seen in a blood test)
- you have an underactive thyroid
- you or a close family member has muscle problems 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.

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 RBX.

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 Statins (such as Pravastatin, Atorvastatin and Simvastatin) and fibrates
- cyclosporin (a medicine which suppresses the immune system)
- phenylbutazone (a medicine to treat pain and inflammation)
- oral hormonal contraceptives containing estrogen / ethinyl estradiol and norethindrone (birth control pills)
- thiazides (fluid or water tablet)
- beta blockers such as atenolol, carvedilol, timolol, metoprolol (used to treat high blood pressure, heart conditions, glaucoma and migraine)

These medicines may be affected by Fenofibrate RBX, 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 RBX.

How to take Fenofibrate RBX

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.

If you have mild to moderate kidney disease, your doctor may tell you to take a lower dose of Fenofibrate.

Ask your doctor or pharmacist about properly taking Fenofibrate RBX.

How to take it

Swallow the tablet(s) whole with a full glass of water.

When to take it

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

Take Fenofibrate RBX 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 RBX 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 RBX, 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 RBX. 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 RBX

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and

pharmacist that you are taking Fenofibrate RBX.

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.

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 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 RBX, 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 RBX 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 RBX 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 RBX.

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

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

Laboratory abnormalities

- 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)].

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
- yellowing of the skin and eyes and dark coloured urine
- blood clot in the leg causing pain, redness or swelling (deep vein thrombosis)
- you pass little or no urine and experience drowsiness, nausea, vomiting, breathlessness

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

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After using Fenofibrate RBX

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 around 25°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 RBX comes in two types of tablets:

FENOFIBRATE RBX 48mg tablet: white to off-white, oval shaped, biconvex film coated tablets debossed with 'RH 37' on one side and plain on the other side.

The 48 mg strength is available in blister packs of 60 tablets.

FENOFIBRATE RBX 145mg tablet: White to off-white, oval shaped, biconvex film coated tablets debossed with 'RH 38' on one side and plain on the other side.

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

Ingredients

Fenofibrate RBX contains either 48 mg or 145 mg of fenofibrate nanoparticles as the active ingredient:

It also contains:

- sodium lauryl sulfate
- hypromellose
- sucrose
- pregelatinized maize starch
- microcrystalline cellulose
- crospovidone
- silicon dioxide
- sodium stearyl fumarate
- opadry AMB OY-B-28920 white

Supplier

Australian Registration Number:

FENOFIBRATE RBX 48mg tablet blister pack AUST R 233493

FENOFIBRATE RBX 145mg tablet blister pack AUST R 233492

Sponsor