

FENOFIBRATE RBX

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FENOFIBRATE RBX?

FENOFIBRATE RBX contains the active ingredient fenofibrate. Fenofibrate is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood. For more information, see Section [1. Why am I using FENOFIBRATE RBX?](#) in the full CMI.

2. What should I know before I use FENOFIBRATE RBX?

Do not use if you have ever had an allergic reaction to FENOFIBRATE RBX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use FENOFIBRATE RBX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FENOFIBRATE RBX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FENOFIBRATE RBX?

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.

More instructions can be found in Section [4. How do I use FENOFIBRATE RBX?](#) in the full CMI.

5. What should I know while using FENOFIBRATE RBX?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, surgeon or pharmacist you visit that you are using FENOFIBRATE RBX.Have your blood fats checked when requested by your doctor to make sure FENOFIBRATE RBX is working.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.Be active by maintaining an exercise program that your doctor or other health professional recommends.
Things you should not do	<ul style="list-style-type: none">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 same condition as you.Do not stop taking FENOFIBRATE RBX, or change the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how FENOFIBRATE RBX affects you.
Drinking alcohol	<ul style="list-style-type: none">Drinking large quantities of alcohol may increase your chance of FENOFIBRATE RBX causing liver problems.
Looking after your medicine	<ul style="list-style-type: none">Keep FENOFIBRATE RBX tablets in the pack until it is time to take them.Store FENOFIBRATE RBX tablets below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FENOFIBRATE RBX

Active ingredient(s): fenofibrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using FENOFIBRATE RBX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FENOFIBRATE RBX.**

Where to find information in this leaflet:

- [1. Why am I using FENOFIBRATE RBX?](#)
- [2. What should I know before I use FENOFIBRATE RBX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FENOFIBRATE RBX?](#)
- [5. What should I know while using FENOFIBRATE RBX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FENOFIBRATE RBX ?

FENOFIBRATE RBX contains the active ingredient fenofibrate. FENOFIBRATE RBX belongs to group of class known as fibric acid derivatives.

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 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 overtime, 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.

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 RBX has been shown to slow the progression of diabetic retinopathy in patients diagnosed with this condition.

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.

2. What should I know before I use FENOFIBRATE RBX ?

Warnings

Do not use FENOFIBRATE RBX if:

- you are allergic to fenofibrate or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- any medicine containing gemfibrozil
- it's after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

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.

Check with your doctor if you:

- have any other medical conditions:
 - liver disease
 - severe kidney disease
 - disease of the gallbladder or pancreas
 - experienced muscular pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides.
- take any medicines for any other condition.
- have any allergies to any other medicines, foods, preservatives or dyes.
- experience allergic reaction to sunlight or UV light (photoallergy) during treatment with fibrates or ketoprofen
- are currently taking another fibrates drug (e.g. gemfibrozil etc)
- have any other 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

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

Check with your doctor if you are pregnant or intend to become pregnant.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children under 18

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 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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 Statins (such as Pravastatin, Atorvastatin and Simvastatin) and fibrates
- ciclosporin (a medicine which suppresses the immune system)
- glitazones (medicines to reduce sugar levels)
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FENOFIBRATE RBX.

4. How do I use FENOFIBRATE RBX?

How much to take / use

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.

Follow the instructions provided and use FENOFIBRATE RBX until your doctor tells you to stop.

When to take / use FENOFIBRATE RBX

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.

How to use FENOFIBRATE RBX

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

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 use FENOFIBRATE RBX

FENOFIBRATE RBX should be used regularly at 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.

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 you missed.

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

If you use too much FENOFIBRATE RBX

If you think that you have used too much FENOFIBRATE RBX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Symptoms of an overdose may include:

- diarrhoea
- nausea

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using FENOFIBRATE RBX?

Things you should do

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

Remind any doctor, dentist or pharmacist or surgeons you visit that you are using FENOFIBRATE RBX.

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 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.

Things you should 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 same condition as you.

Do not stop taking FENOFIBRATE RBX, or change the dosage, without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FENOFIBRATE RBX affects you.

FENOFIBRATE RBX may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid drinking large quantities of alcohol. Drinking large quantities of alcohol may increase your chance of FENOFIBRATE RBX causing liver problems.

Looking after your medicine

Keep the medicine where temperature stays around 25° C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • stomach pain or discomfort • backpain • headache • unusual tiredness or weakness • diarrhoea or constipation • nausea, vomiting • skin reaction, photosensitivity reactions • sore throat and discomfort when swallowing (pharyngitis) • runny or blocked nose, sneezing or facial pressure or pain (rhinitis) • sexual dysfunction • muscular pain or spasms <p>The above list includes the more common side effects of your</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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)].

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> •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 and/or diarrhea(erythema multiforme) • difficulty in breathing • severe abdominal pain • chest pain • temporary paralysis of the muscles • yellowing of the skin and eyes and dark colored 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 <p>The above list includes very serious side effects. You may need urgent medical attention. These side effects are rare.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Who distributes FENOFIBRATE RBX

Sun Pharma ANZ Pty Ltd

12 Waterloo Road Macquarie Park

NSW 2113 Australia

Email: customerservice.aus@sunpharma.com

Tel: 1800 726 229

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7. Product details

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

What FENOFIBRATE RBX contains

Active ingredient (main ingredient)	fenofibrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium lauryl sulfate• hypromellose• sucrose• pregelatinized maize starch• microcrystalline cellulose• crospovidone• silicon dioxide• sodium stearyl fumarate opadry AMB OY-B-28920 white
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What FENOFIBRATE RBX looks like

FENOFIBRATE RBX comes in two types of tablets:

FENOFIBRATE RBX 48mg tablet (AUST R 233493): 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 in blister packs of 60 tablets.

FENOFIBRATE RBX 145mg tablet (AUST R 233492): 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 in blister packs of 30 tablets.