

Ezenol Tablet 160mg

Fenofibrate 160mg

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What Ezenol Tablet 160mg is used for

Ezenol Tablet 160mg 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, Ezenol Tablet 160mg reduces the bad cholesterol and can actually raises the good cholesterol.

Ezenol Tablet 160mg does not reduce the cholesterol that comes from fat in food.

Therefore, when you are taking Ezenol Tablet 160mg, you also need to follow a low fat diet and other measures, such as exercise and weight control.

How Ezenol Tablet 160mg works

Ezenol Tablet 160mg works through the activation of a cell nuclear receptor called PPAR, which reduces the amount of triglycerides and bad cholesterol made in the body and increases the good cholesterol.

Ezenol Tablet 160mg 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 use Ezenol Tablet 160mg

- When you must not use it

Do not take Ezenol Tablet 160mg 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 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 Ezenol Tablet 160mg 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

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other medicines used to treat high cholesterol or triglycerides	prescription from your pharmacy, supermarket or health food store.	before treatment with Ezenol Tablet 160mg should be continued.
Do not give Ezenol Tablet 160mg to anyone under the age of 18 years.	Some medicines and Ezenol Tablet 160mg may interfere with each other. These include:	Take Ezenol Tablet 160mg 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.
The safety and effectiveness of Ezenol Tablet 160mg in children has not been established.	- oral anti-coagulants (medicines used to prevent blood clots) - other cholesterol regulating medicines including fibrates - cyclosporin (a medicine which suppresses the immune system)	<u>- How long to use it</u>
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.	These medicines may be affected by Ezenol Tablet 160mg, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.	Continue taking your medicine for as long as your doctor or pharmacist tells you. Ezenol Tablet 160mg 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 Ezenol Tablet 160mg, your levels may become abnormal again.
<u>- Before you start to use it</u>	Your doctor has more information on medicines to be careful with or to avoid while taking Ezenol Tablet 160mg.	<u>- If you forget to use it</u>
Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.	How to use Ezenol Tablet 160mg	If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
Tell your doctor or pharmacist if you have or have had any of the following medical conditions:	Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.	Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.
- kidney problems - muscular aching, tenderness or weakness not caused by exercise	If you do not understand the instructions on the box, ask your doctor or pharmacist for help.	Do not take a double dose to make up for the dose that you missed.
Tell your doctor if you are pregnant, intend to become pregnant or are breastfeeding.	<u>- How much to use</u>	This may increase the chance of getting an unwanted side effect.
Your doctor can discuss the risks and benefits involved.	The initial recommended dose is 160 mg daily, taken as 1 x 160 mg tablet.	If you are not sure what to do, ask your doctor or pharmacist.
If you have not told your doctor about any of the above, tell them before you take Ezenol Tablet 160mg.	<u>- When to use it</u>	
<u>- Taking other medicines</u>	Ezenol Tablet 160mg can be taken at any time of the day, with or without food. Any dietary measures started	

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If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

- If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Ezenol Tablet 160mg. 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 it

- Things you must do

Have your blood fats checked when requested by your doctor to make sure Ezenol Tablet 160mg is working.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ezenol Tablet 160mg.

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 Ezenol Tablet 160mg, or change the dosage, without checking with your doctor.

- Things to be careful of

Avoid drinking large quantities of alcohol while you are taking this

medicine. Drinking large quantities of alcohol may increase your chance of Ezenol Tablet 160mg causing liver problems.

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 Ezenol Tablet 160mg

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
- Nausea

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- Skin reactions
- Photosensitivity reactions

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
- 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.

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Ezenol Tablet 160mg

- 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

An oblong, white film coated tablet with 'FENO' on one side and plain on other side.

Ezenol Tablet 160mg comes in a blister packing of 3 x 10 tablets.

- Ingredients

-Active ingredient(s):

- Fenofibrate

- Inactive ingredients:

- Corn Starch
- Sodium Stearyl Fumarate
- Colloidal Silicon Dioxide
- Povidone 30

- Purified Water
- Lactose Monohydrate
- Microcrystalline Cellulose
- Croscarmellose Sodium
- Sodium Lauryl Sulfate / Sodium Lauryl Sulphate
- Croscarmellose Sodium
- Opadry White

- MAL number:

MAL14085013AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd
Lot No. 2 & 4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor.

Product Registration Holder

Duopharma Marketing Sdn. Bhd Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor.

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