

PART III: CONSUMER INFORMATION

EZETROL®
ezetimibe tablets

This leaflet is part III of a three-part “Product Monograph” published when EZETROL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EZETROL®. Contact your doctor or pharmacist if you have any questions about the drug.

Remember that your doctor has prescribed this medicine for you. Never give it to anyone else.

ABOUT THIS MEDICATION**What the medication is used for:**

EZETROL® helps to reduce the amount of cholesterol and triglycerides in your blood in conjunction with lifestyle changes including exercise, diet, and weight management, when a response to such changes has been inadequate.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of low density lipoprotein cholesterol and high density lipoprotein cholesterol (LDL and HDL cholesterol).

LDL cholesterol is often called “bad” cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.

HDL cholesterol is often called “good” cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Triglycerides are another form of fat in your blood that may increase your risk for heart disease.

EZETROL® may be taken alone or with other cholesterol-lowering medicines known as *statins* or with another medicine known as fenofibrate, in addition to diet and other lifestyle changes (see INTERACTIONS WITH THIS MEDICATION). EZETROL® adds to the cholesterol-lowering effect of statins and fenofibrate. Statins and fenofibrate lower cholesterol in a different way; they work in the liver.

What it does:

EZETROL® works by decreasing the absorption of cholesterol in the small intestine.

When it should not be used:

- Patients who are hypersensitive (allergic) to ezetimibe or any of the nonmedicinal ingredients should not take EZETROL®.
- Patients with liver disease, active or unexplained increases in liver enzymes (blood tests of liver function) should not take EZETROL® together with a statin.

- Patients who are pregnant should not take EZETROL® together with a statin.
- Patients who are nursing should not take EZETROL® together with a statin.

What the medicinal ingredient is:

Ezetimibe.

What the important nonmedicinal ingredients are:

Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.

What dosage forms it comes in:

Tablet 10 mg (white to off-white).

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- Liver disease (Hepatitis)
- Pancreas disease (Pancreatitis)
- Muscle pain (Myopathy/Rhabdomyolysis, myalgia)
- Severe allergic reaction (Anaphylaxis)

Before you use EZETROL® talk to your doctor if you:

- are pregnant, plan to become pregnant or think you might be pregnant.
- are breast-feeding. EZETROL® may be passed in your milk to your baby.
- have now or have had in the past any medical problems (including liver disease or liver problems).

INTERACTIONS WITH THIS MEDICATION

You should always tell your doctor about all drugs that you are taking or plan to take as well as those obtained without a prescription.

Drugs that may interact with EZETROL® include:

- Cyclosporine
- Cholestyramine (a resin/bile acid sequestrant) or any other bile acid sequestrant. In that case, EZETROL® should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.
- Fibrates

PROPER USE OF THIS MEDICATION**Usual dose:**

- EZETROL® should be taken as directed. Take one 10 mg tablet by mouth each day, preferably at the same time of day. EZETROL® can be taken with or without food.
- Continue taking your other cholesterol-lowering medicines known as statins or fenofibrate unless your doctor tells you to stop.
- If you are taking a statin or fenofibrate, EZETROL® can be taken at the same time.
- Even if you are taking medication to treat high cholesterol, it is important to have your cholesterol measured regularly. You should also know your cholesterol levels and goals.

Overdose:

Take EZETROL® only as prescribed for you. If you take more EZETROL® than you were prescribed, contact your doctor or pharmacist.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, just resume the usual schedule of one tablet daily.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

EZETROL® is generally well tolerated.

- When used alone, the following common side effects have been reported: abdominal pain; diarrhea; flatulence; tiredness; viral infection; throat infection (pharyngitis); nose infection (sinusitis); joint pain (arthralgia); back pain; and coughing.

The following uncommon side effects have been reported: elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function; indigestion; heartburn; nausea; muscle spasms; neck pain; decreased appetite; hot flush; high blood pressure; chest pain and pain.

- When used with a statin, the following common side effects have been reported: headache; tiredness; abdominal pain; diarrhea; joint pain (arthralgia); muscle pain (myalgia); back pain; throat infection (pharyngitis); nose infection (sinusitis); upper chest infection (respiratory tract); and changes in certain laboratory blood tests.

The following uncommon side effects have been reported: tingling sensation; dry mouth; gastritis; itching; rash; hives; muscular weakness; pain in arms and legs; unusual tiredness or weakness; and swelling, especially in the hands and feet.

When used with fenofibrate, the following side effect was reported: abdominal pain

- In general use, the following side effects have been reported: raised red rash, sometimes with target-shaped lesions; dizziness; depression; tingling sensation; constipation; and unusual tiredness or weakness.
- You should contact your doctor if you develop persistent and severe muscle aches or pains with no obvious explanation at any time after starting to take EZETROL®.

If you are prescribed EZETROL® with a statin, your doctor will order routine blood tests to check your liver function before and after starting treatment.

Talk to your doctor anytime you have a medical problem you think may be related to EZETROL®.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptoms / effects	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Rare			
Muscle aches and pains (Myopathy/Rhabdomyolysis)	√		
Sudden severe allergic reactions (swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash and hives).			√
Symptoms of liver problems (severe abdominal pain, especially if felt on the upper right side below the ribs, dark urine, general itchiness, severe nausea or vomiting, pale stools, yellowing of skin or eyes)		√	
Symptoms of gallstones or inflammation of the gallbladder (severe abdominal pain, nausea, vomiting)		√	
Symptoms of pancreas problems (severe abdominal pain)		√	

This is not a complete list of side effects. For any unexpected effects while taking EZETROL[®], contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine between 15°C and 30°C. Protect from moisture.

Keep EZETROL[®] and all medicines out of the reach of children.

Do not use this medicine after the date shown following EX (or EXP) on the container.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9
Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

You may obtain further information from your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at: www.organon.ca or by contacting the sponsor, Organon Canada Inc., at: 1-844-820-5468.

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