

PART III: CONSUMER INFORMATION

Pr **EZETIMIBE**
Ezetimibe tablets

This leaflet is part III of a three-part "Product Monograph" published when EZETIMIBE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EZETIMIBE. 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:

EZETIMIBE 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.

EZETIMIBE 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). EZETIMIBE 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:

EZETIMIBE 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 EZETIMIBE.

- Patients with liver disease, active or unexplained increases in liver enzymes (blood tests of liver function) should not take EZETIMIBE together with a statin.
- Patients who are pregnant should not take EZETIMIBE together with a statin.
- Patients who are nursing should not take EZETIMIBE together with a statin.

What the medicinal ingredient is:

Ezetimibe

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

Tablet 10 mg (white, oval tablets with debossing "10" on one side and "EZT" on the other side).

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 EZETIMIBE talk to your doctor if you:

- are pregnant, plan to become pregnant or think you might be pregnant.
- are breast-feeding. EZETIMIBE 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 EZETIMIBE include:

- **Cyclosporine**
- Cholestyramine (a resine/bile acid sequestrant) or any other bile acid sequestrant. In that case, EZETIMIBE 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:

- EZETIMIBE should be taken as directed. Take one 10 mg tablet by mouth each day, preferably at the same time of day. EZETIMIBE 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, EZETIMIBE 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 EZETIMIBE only as prescribed for you. If you take more EZETIMIBE 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

EZETIMIBE 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 EZETIMIBE.

If you are prescribed EZETIMIBE 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 EZETIMIBE.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		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 EZETIMIBE contact your doctor or

pharmacist.

HOW TO STORE IT

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

Keep this medication out of reach of children.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701E
 - Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc. at:

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