

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **EZETROL**[®]

ezetimibe tablets

Read this carefully before you start taking **EZETROL**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **EZETROL**.

Serious Warnings and Precautions

EZETROL can cause serious side effects including:

- **Liver problems such as Drug induced liver injury and hepatitis**
- **Pancreatitis (inflammation of the pancreas)**
- **Serious muscle problems (myopathy, rhabdomyolysis and myalgia).** If you/your child have previously taken a statin and had persistent or severe muscle pain with no obvious cause, your healthcare professional may monitor you/your child for signs of serious muscle problems.
- **Severe allergic reactions**
- **Serious skin reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug reaction with eosinophilic and systemic symptoms (DRESS)**

See the “**Serious side effects and what to do about them**” table, below, for more information on these and other serious side effects.

What is EZETROL used for?

EZETROL is used along with a change in diet and lifestyle to lower the level of cholesterol and other fats (such as triglycerides) in the blood of children (10 years of age and older) and adults. In these children and adults, diet and other lifestyle changes alone were not effective in lowering their cholesterol.

EZETROL may be used alone or with other cholesterol lowering medicines called statins or fenofibrate.

How does EZETROL work?

EZETROL belongs to a group of medicines called cholesterol absorption inhibitors. It works by lowering the amount of cholesterol that is absorbed in the small intestine.

What are the ingredients in EZETROL?

Medicinal ingredient: Ezetimibe

Non-medicinal ingredients: Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.

EZETROL comes in the following dosage forms:

Tablet 10 mg (white to off-white).

Do not use EZETROL if:

- you/your child are allergic to ezetimibe or any of the nonmedicinal ingredients in EZETROL.
- you/your child are taking a statin and have liver disease and/or active or unexplained increases in liver enzymes (blood tests of liver function).
- you are pregnant and taking a statin or fenofibrate.
- you are nursing and taking a statin or fenofibrate.
- are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 because lactose is a non-medicinal ingredient in EZETROL.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take EZETROL. Talk about any health conditions or problems you/your child may have, including if you/your child:

- are pregnant, plan to become pregnant or think you might be pregnant.
- are breast-feeding or are planning to breast-feed. EZETROL may be passed in your milk to your baby.
- have liver problems.
- are taking fibrates other than fenofibrate. Talk to your healthcare professional if you are not sure.
- have previously taken a statin and had persistent or severe muscle pain with no obvious cause.

Other warnings you should know about:

Liver function tests: If you/your child are taking EZETROL alone or with a statin or fenofibrate, your healthcare professional may do liver function tests before and during treatment. This is to check and monitor the health of the liver.

Gallbladder problems: Taking EZETROL and fenofibrate may cause gallbladder problems such as gallstones. Talk to your healthcare professional **right away** if you/your child has:

- severe abdominal pain
- nausea
- vomiting

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

If you/your child are taking EZETROL with cyclosporine, your healthcare professional will monitor the amount of cyclosporine in your/their body.

The following may interact with EZETROL:

- Bile acid sequestrants such as cholestyramine
- Fibrates

How to take EZETROL:

- Always take EZETROL exactly as your healthcare professional tells you.
- Take EZETROL with or without food but preferably at the same time each day.

- Keep taking your other cholesterol-lowering medicines known as statins or fenofibrate unless your healthcare professional tells you to stop. You can take EZETROL at the same time as the statin or fenofibrate.
- If you/your child are also taking a bile acid sequestrant, take/give EZETROL 2 hours before or at least 4 hours after taking the bile acid sequestrant.
- Carefully follow any measures that your healthcare professional has recommended for diet, exercise or weight control.

Usual dose:

Usual dose (children 10 years of age and older and adults): Take one 10 mg tablet each day.

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:

If you think you, or a person you are caring for, have taken too much EZETROL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child miss a dose, skip the missed dose. Take your/give their next dose as scheduled. Do not take/give two doses at the same time to make up for the missed dose.

What are possible side effects from using EZETROL?

These are not all the possible side effects you may have when taking EZETROL. Some of these side effects may occur when taking EZETROL or when taking EZETROL with a statin or fenofibrate. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal pain
- diarrhea
- flatulence
- viral infection, throat infection (pharyngitis), nose infection (sinusitis) or upper chest infection
- pain including back pain, neck pain, joint pain (arthralgia), chest pain and pain in the arms and legs
- coughing
- elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function
- indigestion or heartburn
- nausea
- muscle spasms or weakness
- decreased appetite
- hot flush
- high blood pressure
- dizziness
- depression
- constipation
- unusual tiredness or weakness

- headache
- tingling sensation usually in the hands, arms, legs or feet
- dry mouth
- gastritis
- rash, hives or itching swelling, especially in the hands and feet

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Erythema multiforme (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center; possibly swollen lips, mild itching or burning		√	
Gallbladder problems: severe abdominal pain, nausea, vomiting, fever, pain that radiates to your shoulder or back, severe pain in your upper right abdomen		√	
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		√	
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen		√	
Serious muscle problems (myopathy, rhabdomyolysis, myalgia): aching muscle, tenderness or weakness that you cannot explain, red-brown (tea coloured) urine	√		
Serious skin reactions (Stevens Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug reaction with eosinophilia and systemic symptoms (DRESS)): serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever; skin rash with pink-red			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
blotches especially on palms of hands or soles of feet, which may blister. You may also have flu-like symptoms at the same time, such as fever, chills or aching muscle.			
Severe allergic reactions: swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing, rash and hives			√
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your/their daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

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.

If you want more information about EZETROL:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

Last Revised JAN 16, 2024

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