

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**LIPIDIL EZ<sup>®</sup>**

**fenofibrate, NanoCrystal<sup>®</sup> formulation tablets**

Read this carefully before you start taking **LIPIDIL EZ<sup>®</sup>** 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 **LIPIDIL EZ<sup>®</sup>**.

**What is LIPIDIL EZ<sup>®</sup> used for?**

LIPIDIL EZ<sup>®</sup> is used in adults, including adults with type 2 diabetes, to lower cholesterol and blood fat levels.

LIPIDIL EZ<sup>®</sup> is used together with ezetimibe to lower cholesterol in adults with a specific type of high cholesterol called “mixed hyperlipidemia”.

LIPIDIL EZ<sup>®</sup> is to be used together with dietary and lifestyle changes.

**How does LIPIDIL EZ<sup>®</sup> work?**

LIPIDIL EZ<sup>®</sup> lowers cholesterol by reducing the amount of bad cholesterol (LDL) and fatty substances in the blood (triglycerides). It also increases the amount of good cholesterol (HDL) in the blood.

**What are the ingredients in LIPIDIL EZ<sup>®</sup>?**

Medicinal ingredient: fenofibrate

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, docusate sodium, D&C Yellow #10 Aluminum Lake (48 mg tablet), FD&C yellow #6/sunset yellow FCF Aluminum Lake (48 mg tablet), FD&C Blue #2/Indigo carmine FCF Aluminum Lake (48 mg tablet), hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium lauryl sulfate, soybean lecithin, sucrose, talc, titanium dioxide, xanthan gum.

**LIPIDIL EZ<sup>®</sup> comes in the following dosage forms:**

Film-coated tablets: 48 mg and 145 mg

**Do not use LIPIDIL EZ<sup>®</sup> if you:**

- have serious liver or kidney problems;
- have gallbladder problems;
- have pancreatitis (an inflamed pancreas which causes abdominal pain);
- are allergic (hypersensitive) to fenofibrate or similar drugs or if you are allergic to any of the ingredients in LIPIDIL EZ<sup>®</sup>;
- are allergic (hypersensitive) to peanuts, arachis oil, soya lecithin, lactose or related products

due to risk of allergic reaction;

- are pregnant, think you may be pregnant or are planning to get pregnant. If you get pregnant while taking LIPIDIL EZ<sup>®</sup>, contact your healthcare professional immediately.
- are breast-feeding or planning to breast-feed;
- have a photoallergy (skin sensitivity to sunlight or UV light) when taking a fibrate (a class of drugs used for lowering cholesterol, which includes LIPIDIL EZ<sup>®</sup> and gemfibrozil) or an anti-inflammatory drug called ketoprofen;
- are taking statins (another type of drug used to lower cholesterol) and have muscle problems or have potential risks of developing muscle problems;
- are under 18 years of age.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LIPIDIL EZ<sup>®</sup>. Talk about any health conditions or problems you may have, including if you:**

- have liver or kidney problems;
- have pancreas problems;
- have gallstones;
- have thyroid problems;
- LIPIDIL EZ<sup>®</sup> contains lactose and sucrose. Talk to your healthcare professional before taking LIPIDIL EZ<sup>®</sup> if you have been told that you cannot tolerate or digest some sugars.

**Other warnings you should know about:**

You should have regular check-ups with your healthcare professional while taking LIPIDIL EZ<sup>®</sup>. Your healthcare professional will also do regular blood work to make sure you are responding well to LIPIDIL EZ<sup>®</sup> and that you are not experiencing side effects. These side effects can include serious muscle problems, which can cause kidney damage or even death. The risk of muscle problems is higher in some patients. Tell your healthcare professional if you:

- are over 70 years old;
- have kidney or liver problems;
- have thyroid problems;
- or a close family member has muscle problems which run in the family;
- drink large amounts of alcohol;
- have a serious infection or have recently had surgery or suffered a trauma;
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
- are taking drugs called statins to lower cholesterol such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin;
- have ever had muscle problems during treatment with fibrates such as fenofibrate, bezafibrate or gemfibrozil.

While taking LIPIDIL EZ<sup>®</sup> if you experience muscle pain, tenderness or weakness, especially with a fever, contact your healthcare professional immediately.

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

**The following may interact with LIPIDIL EZ®:**

- Statins (other drugs used to lower cholesterol) such as atorvastatin, pravastatin, simvastatin, etc. Taking a statin at the same time as LIPIDIL EZ® may increase the risk of serious muscle problems.
- Blood thinners, such as warfarin;
- Cyclosporine (a drug which may be taken following an organ transplant);
- Cholestyramine or similar drugs (used to lower cholesterol);
- Estrogens (hormones which may be found in birth control pills or hormone replacement therapy);
- Some drugs used to treat diabetes, such as rosiglitazone or pioglitazone.

**How to take LIPIDIL EZ®:**

- LIPIDIL EZ® can be taken with or without food.
- Swallow the tablet whole with a glass of water.
- Do not crush or chew the tablet.

**Usual adult dose:**

- The recommended dose of LIPIDIL EZ® is one 145 mg tablet daily.
- If you are elderly or have kidney problems the recommended dose is one 48 mg tablet daily.

**Overdose:**

If you think you have taken too much LIPIDIL EZ®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**What are possible side effects from using LIPIDIL EZ®?**

These are not all the possible side effects you may feel when taking LIPIDIL EZ®. If you experience any side effects not listed here contact your health care professional.

Side effects may include:

- Stomach pain, constipation, diarrhea, gas
- Nausea, vomiting
- Headache
- Dizziness
- Fatigue
- Trouble sleeping
- Low sex drive
- Skin rashes, redness and itching, sensitivity of the skin to light
- Hair loss
- Weight loss

- Joint pain

LIPIDIL EZ<sup>®</sup> can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Allergic reaction:</b> swelling of the face, lips, tongue or throat, which may cause difficulty in breathing			✓
<b>Blood clot in the lung:</b> sudden chest pain and trouble breathing			✓
<b>Blood clot in the leg:</b> pain, redness or swelling in the legs			✓
<b>Inflammation of the pancreas:</b> stomach pain that lasts and gets worse when you lie down, nausea, vomiting			✓
<b>RARE</b>			
<b>Serious muscle problems:</b> muscle pain or cramps, or muscle weakness, especially together with fever and generally feeling unwell			✓
<b>Liver problems:</b> yellowing of the skin and whites of the eyes, dark urine			✓

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

### **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 \(www.healthcanada.gc.ca/medeffect\)](http://www.healthcanada.gc.ca/medeffect);
- 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](http://www.healthcanada.gc.ca/medeffect).

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

### **Storage:**

Store at 15 to 30°C. Protect from light and moisture.

Keep out of reach and sight of children.

### **If you want more information about LIPIDIL EZ®:**

- 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 ([www.healthcanada.gc.ca](http://www.healthcanada.gc.ca)); the manufacturer's website ([www.mylan.ca](http://www.mylan.ca)), or by calling 1-844-596-9526

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Last Revised January 31, 2017