

INFORMATION FOR THE CONSUMER

Full prescribing information is available to doctors and pharmacists on request.

LIPIDIL EZ reduces levels of low density cholesterol (LDL-C or bad cholesterol), and other lipids called triglycerides (fatty substances found in the blood), while increasing levels of high density cholesterol (HDL-C or good cholesterol) in the blood.

LIPIDIL EZ is used, in conjunction with the appropriate diet, in the treatment of adult patients with :

- a. type 2 diabetes (non-insulin dependent), with dyslipoproteinemia (abnormal lipid levels in the blood, including high cholesterol), with or without elevated triglycerides, Fredrickson classification types IIa and IIb);
- b. high serum triglyceride levels (Fredrickson classification types IV and V), who are at high risk for complications.

LIPIDIL EZ may be taken with another medicine known as ezetimibe, in addition to diet and other lifestyle changes. Ezetimibe adds to the cholesterol-lowering effect of LIPIDIL EZ. Ezetimibe works by decreasing the absorption of cholesterol in the small intestine. LIPIDIL EZ lowers cholesterol in a different way; it works in the liver.

LIPIDIL EZ is only available on prescription. This medicine should only be used to supplement an appropriate diet recommended and followed up by your doctor for the long-term treatment of raised lipid levels; prescription of this medicine in no way replaces dietary treatment. In addition, depending on the situation, your doctor may recommend further physical exercise, weight loss or other lifestyle measures.

Take exactly as instructed by your doctor. Do not change the dose without your doctor's advice. Consult your doctor before stopping treatment.

DO NOT USE LIPIDIL EZ IF:

- you suffer from liver or kidney disease;
- you already have gallbladder problems;
- you are allergic to fenofibrate or similar drug or if you are allergic to any of the ingredients in LIPIDIL EZ tablets (***see What Does LIPIDIL EZ Contain?***)
- you are allergic to peanuts or arachis oil or soya lecithin or related products due to risk of allergic reaction.
- you are pregnant or breastfeeding; in the event of pregnancy during treatment, your doctor should be informed and LIPIDIL EZ should be discontinued;
- you 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 and gemfibrozol) or an anti-inflammatory drug called ketoprofen.

BEFORE STARTING TREATMENT WITH THIS MEDICINE, your doctor must know:

- if you have had an allergic reaction to (or poorly tolerated) LIPIDIL EZ, **any of its ingredients** (see ***What Does LIPIDIL EZ Contain?***), or any other lipid treatment;
- if you suffer from liver or kidney problems;
- if you have a gallbladder or gallstone problem;
- if you are pregnant, or intend to become pregnant, or are breast-feeding, or intend to breast-feed;
- if you are taking any other medicine, prescription or non-prescription. Of particular concern are:
 - Statins (a class of drugs, which includes atorvastatin, pravastatin, simvastatin, etc., used to lower cholesterol)
 - Oral anticoagulants (blood thinning agents, such as warfarin)
 - Cyclosporine (a drug which may be taken following an organ transplant)
 - Cholestyramine or similar drug (another type of cholesterol lowering agent)
 - Estrogens (hormones which may be found in oral contraceptives or hormone replacement therapy)
 - Rosiglitazone (a drug used to treat type 2 diabetes)

PROPER USE OF THE MEDICINE

- LIPIDIL EZ (NanoCrystal[®] formulation) may be taken once daily, anytime, with or without food.
- The usual recommended dose of LIPIDIL EZ in adults is one 145 mg tablet.
- In elderly patients and those with mild to moderate kidney disease, the doctor may initiate treatment with one 48 mg tablet daily, taken anytime, with or without food. The doctor may later decide to increase this dose.
- Never change the dose unless directed by your doctor.
- LIPIDIL EZ is not recommended for use in children.
- The safety of using LIPIDIL EZ in combination with a statin has not been extensively studied in patients. Therefore, the combined use of fenofibrate with a statin should be avoided unless recommended by your doctor.
- Another type of cholesterol lowering agent called ezetimibe can also be taken with LIPIDIL EZ.
- Tell your doctor about any health problem that occurs while you are taking LIPIDIL EZ. If you need other medical treatment while taking LIPIDIL EZ, let your doctor know that you are taking LIPIDIL EZ.

SIDE EFFECTS

In addition to its intended action, any medicine may cause side effects.

Tell your doctor if you feel in any way unwell while taking LIPIDIL EZ.

Some common side effects may include abdominal pain, constipation, diarrhea, nausea, headache, dizziness, skin reactions and fatigue. This is not a complete list of side effects. If you experience any unexpected symptoms while taking LIPIDIL EZ, contact your doctor or pharmacist.

Muscle pain or cramps, or muscle weakness, may indicate rare, but more serious, side effects. If you suffer any unexplained muscle pain, stop the drug and contact your doctor immediately.

Your doctor will ask you to have regular medical check-ups and appropriate laboratory tests. It is important to respect the dates proposed for these tests: we strongly recommend that you keep these appointments faithfully so that any abnormalities that may occur can be identified promptly.

WHAT DOES LIPIDIL EZ CONTAIN?

LIPIDIL EZ contains, in addition to fenofibrate, the following nonmedicinal ingredients: crospovidone, docusate sodium, hypromellose, lactose monohydrate, magnesium stearate, colloidal silicon dioxide, microcrystalline cellulose, sodium lauryl sulfate, sucrose.

The tablet coating for the 145 mg tablets contains polyvinyl alcohol, titanium dioxide, talc, soybean lecithin, xanthan gum.

The tablet coating for the 48 mg tablets contains polyvinyl alcohol, titanium dioxide, talc, lecithin, D&C Yellow #10 Aluminum Lake, D&C yellow #6/sunset yellow FCF Aluminum Lake, D&C Blue #2/Indigo carmine FCF Aluminum Lake

THIS MEDICINE IS PRESCRIBED FOR A PARTICULAR HEALTH PROBLEM AND FOR YOUR PERSONAL USE. DO NOT GIVE IT TO OTHER PERSONS. KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

IF YOU WANT FURTHER INFORMATION, ASK YOUR DOCTOR OR PHARMACIST.

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