

INFORMATION FOR THE CONSUMER

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

LIPIDIL SUPRA reduces blood cholesterol, in particular cholesterol associated with low and very low density lipoproteins (bad cholesterol). LIPIDIL SUPRA reduces high triglyceride levels associated with hypercholesterolemia (excess of cholesterol in the blood) and increases the high density lipoprotein (HDL) cholesterol fraction (good cholesterol). Because of the effects on these parameters, LIPIDIL SUPRA is indicated for the treatment of dyslipoproteinemia (abnormal lipoproteins in the blood) in adult patients with type 2 diabetes. Blood uric acid levels are also reduced by LIPIDIL SUPRA treatment.

LIPIDIL SUPRA 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 measures.

Take exactly as instructed by your doctor. Do not change the dose without your doctor's advice. Consult your doctor before stopping treatment since to do so may result in an increase in your blood lipid levels.

DO NOT USE LIPIDIL SUPRA 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 SUPRA tablets (See **What Does LIPIDIL SUPRA 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 SUPRA 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 SUPRA and gemfibrozil) 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 SUPRA, **any of its ingredients** (See **What Does LIPIDIL SUPRA Contain?**), or any other lipid treatment.
- if you suffer from liver or kidney problems;
- if you have a gall bladder 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 other medicines, prescription or non-prescription. Of particular concern are:
 - Statins (a class of drugs, which includes atorvastatin, pravastatin, simvastatin, etc., used to lower cholesterol)

- Ezetimibe (another type of cholesterol lowering agent)
- 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 SUPRA should be taken with meals, as directed by your doctor.
- It is particularly important to follow this advice because fenofibrate is less well absorbed and hence less effective when not taken with food.
- The usual recommended dose of LIPIDIL SUPRA in adults is one 160 mg tablet.
- Never change the dose unless directed by your doctor.
- LIPIDIL SUPRA is not recommended for use in children.
- The safety of using LIPIDIL SUPRA 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.
- Tell your doctor about any health problem that occurs while you are taking LIPIDIL SUPRA. If you need other medical treatment while taking LIPIDIL SUPRA, let your doctor know that you are taking LIPIDIL SUPRA.

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 SUPRA.

Some common side effects may include abdominal pains, 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 SUPRA, 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 SUPRA CONTAIN

LIPIDIL SUPRA contains, in addition to fenofibrate, the following nonmedicinal ingredients: povidone, lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, sodium stearyl fumarate and sodium lauryl sulfate.

The tablet coating for the 100 mg and 160 mg tablets contain polyvinyl alcohol, titanium dioxide, talc, soybean lecithin, xanthan gum.

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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Last revised: July 15, 2011