INFORMATION FOR THE CONSUMER

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

LIPIDIL SUPRA® (fenofibrate, microcoated formulation) 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 have liver or kidney problems;
- you have gallbladder problems;
- you have pancreatitis (an inflamed pancreas which causes abdominal pain);
- 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 (hypersensitive) to peanuts or arachis oil or soya lecithin or related products due to risk of allergic reaction;
- you are pregnant, think you may be pregnant or are planning to have a baby; in the event of pregnancy during treatment, your doctor should be informed and LIPIDIL SUPRA® should be discontinued;
- you are breast-feeding or planning to breast-feed your baby.
- 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 gemfibrozol) or an anti-inflammatory drug called ketoprofen.
- you are taking statins and have muscle problems or have potential risks of developing muscle problems.
- you are under 18 years of age.

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 an inflamed liver (hepatitis) - signs include yellowing of the skin and the whites of the eyes (jaundice) and an increase in liver enzymes (shown in blood tests);
- if you have pancreas problems;
- if you have a gall bladder or gallstone problem;
- if you have an under-active thyroid gland (hypo-thyroidism);
- 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). Taking a statin at the same time as LIPIDIL SUPRA® may increase the risk of muscle problems
    - 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)
    - a particular class of medicines to treat diabetes (such as rosiglitazone or pioglitazone)

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. These problems can include muscle inflammation and breakdown, which can cause kidney damage or even death. The risk of muscle breakdown is higher in some patients. Tell your doctor if:

- you are over 70 years old;
- you have kidney problems;
- you have thyroid problems;
- you or a close family member has muscle problem which runs in the family;
- you drink large amounts of alcohol;
- you are taking medicines called statins to lower cholesterol such as simvastatin, atorvastatin, pravastatin, rosuvastatin or fluvastatin;
- you have ever had muscle problems during treatment with fibrates such as fenofibrate, bezafibrate or gemfibrozil.

PROPER USE OF THE MEDICINE:

- LIPIDIL SUPRA® should be taken with meals, as directed by your doctor. Swallow the tablet with a glass of water. Do not crush or chew the tablet.

- It is particularly important to follow this advice because fenofibrate is less well absorbed and hence less effective when not taken with food.
- The recommended dose of LIPIDIL SUPRA® is one 160 mg tablet daily.
- 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 you doctor know that you are taking LIPIDIL SUPRA®.
- 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.

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 pain, constipation, diarrhea, flatulence, nausea, vomiting, headache, dizziness, skin reactions, fatigue and raised levels of liver enzymes in the blood. This is not a complete list of side effects. If you experience any unexpected symptoms while taking LIPIDIL SUPRA®, contact your doctor or pharmacist.

Stop taking LIPIDIL SUPRA® and see a doctor straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:
- allergic reaction - the signs may include swelling of the face, lips, tongue or throat, which may cause difficulty in breathing
- stomach pain - this may be a sign that your pancreas is inflamed (pancreatitis)
- chest pain and feeling breathless - these may be signs of a blood clot in the lung (pulmonary embolism)
- pain, redness or swelling in the legs - these may be signs of a blood clot in the leg (deep vein thrombosis)
- yellowing of the skin and whites of the eyes (jaundice), or an increase in liver enzymes - these may be signs of an inflamed liver (hepatitis).

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.

WHAT DOES LIPIDIL SUPRA® CONTAIN?

LIPIDIL SUPRA® contains, in addition to fenofibrate, the following non-medicinal ingredients: povidone, lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, sodium stearyl fumerate and sodium lauryl sulfate.

The tablet coating for the 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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