

LIPANTHYL 160 mg, film-coated tablet

Please, read all of this leaflet carefully before taking this medicine.

- Keep this leaflet, you may need to read it again.
 - If you have any other questions or are in doubt, ask your doctor or pharmacist for further information.
- This medicine has been prescribed for you personally. Never give it to anybody else, even in the case of identical symptoms, because it could be harmful for them.

LIPANTHYL 160 mg, film-coated tablet

The active ingredient is: Fenofibrate (160 mg)

The other components are: Sodium laurilsulfate, monohydrate lactose, povidone, silicified microcrystalline cellulose, anhydrous colloidal silica, crospovidone, sodium stearyl fumarate.

Composition of the coating: OPADRY®: polyvinyl alcohol, titanium dioxide (E171), talcum, soybean lecithin, xanthan gum.

Holder:

Laboratoires FOURNIER S.A.
28, boulevard Clemenceau
21000 DIJON, FRANCE

Manufacturer:

RECIPHARM FONTAINE
Rue des Prés Potets
21121 FONTAINE LES DIJON, FRANCE

WHAT IS LIPANTHYL 160 mg, film-coated tablet AND IN WHAT CASES SHOULD IT BE USED?

This medicine is on the form of film coated tablets. Box of 30 tablets.

This medicine is a serum lipid reducing agent/cholesterol and triglyceride reducer/fibrate.

This medicine is recommended for certain hypercholesterolemias (abnormally high rate of cholesterol in the blood) and/or hypertriglyceridemias (increase of triglycerides – fats – in the blood) in adults, when a suitable and assiduously followed diet has failed.

WHAT ARE THE NECESSARY INFORMATION BEFORE TAKING LIPANTHYL 160 mg, film-coated tablet

LIPANTHYL 160 mg, film-coated tablet must not be used in the following cases:

- Hepatic insufficiency (disturbances of liver function),
- Renal insufficiency (disturbances of kidney function),
- Known allergy to fenofibrate, soybean lecithin, peanuts, peanut oil or any of the excipients of this medicine,
- Known phototoxicity or photoallergic reactions (cutaneous reactions during exposure to the sun or artificial UV light) during treatment with fenofibrate or a medicine with a similar structure, in particular ketoprofen (anti-inflammatory medicine),
- Presence of gallstones,
- Pancreatitis (inflammation of the pancreas leading to abdominal pain) unless acute pancreatitis is caused by high levels of a type of fat in the blood,
- If you are pregnant or breast-feeding,
- In children.

THIS IS A MEDICAMENT

A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor
- Keep all medicaments out of reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

Take special precautions with LIPANTHYL 160 mg, film-coated tablet

- In case of muscular pains, inform your doctor immediately (see section "What, if any, are the adverse effects?").
 - A liver check-up will be performed before treatment and at regular intervals throughout the first year of treatment. (every 3 months on average)
 - The rate of creatinine must be monitored during the first three months of treatment
- Due to the presence of lactose, this medicine must not be used in cases of galactosemia, glucose and galactose malabsorption syndrome or lactase deficiency (rare metabolic diseases).

Use during pregnancy and breastfeeding

This medicine is contraindicated for pregnant women and during breastfeeding, in the absence of data.

If you found out an unexpected pregnancy while you are taking this medicine, you should interrupt the treatment and consult your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

List of excipients with a noteworthy effect

Lactose, soybean lecithin

Interactions with other medicinal products

To avoid possible interactions between several medicinal products, please inform your doctor or pharmacist if you are taking or have recently taken another medicine, even if it is an over the counter medicine, in particular if you are taking another medicine for cholesterol (fibrate or statin), oral anticoagulants or cyclosporin..

HOW SHOULD LIPANTHYL 160 mg film-coated tablet BE TAKEN?

For adults and elderly patients:

The recommended dosage is one tablet daily.

In patients with renal insufficiency:

A reduced dose is recommended.

In every case, conform strictly to the prescription of your doctor.

If you have the impression that the effect of LIPANTHYL 160 mg film-coated tablet is too strong or too weak, consult your doctor or pharmacist.

To be taken orally.

The treatment is administered in 1 dose per day.

The tablet should be swallowed whole during a meal.

In association with a diet, this medicine constitutes a symptomatic treatment, which should be extended and monitored regularly. For proper use of this medicine, it is essential to undergo regular medical supervision.

If you have taken more of LIPANTHYL 160 mg film-coated tablet than you should have: immediately consult your doctor or pharmacist.

If you forget to take LIPANTHYL 160 mg film-coated tablet: do not take a double dose to make up for the single dose you have forgotten to take.

WHAT, IF ANY, ARE THE ADVERSE EFFECTS?

Like all medicines, LIPANTHYL 160 mg film-coated tablet may have adverse effects:

- gastric or intestinal digestive disturbances (abdominal pains, nausea, vomiting, diarrhoea and flatulence)
- skin reactions (rashes, itching) of an allergic type or photosensitivity reactions (on exposure to the sun or artificial light) on the parts of the body which are exposed to the sun or UV lamps
- temporary rise in transaminases (liver enzymes), jaundice
- muscular pains

If you notice muscular pains, painful muscular sensibility or muscular weakness, please immediately inform your doctor because the muscular problems can be grave in any rare cases.

- in rare cases: gallstones, hepatitis, impotence, pancreatitis, hair loss, interstitial pneumopathies
- increases in the rate of creatinine and urea in the blood, as well as a decrease in the rate of haemoglobin and the number of white cells may be observed,
- pancreatitis (inflammation of the pancreas leading to abdominal pain),
- Thromboembolism : pulmonary embolism (blood clot in the lung causing chest pain and breathlessness), deep vein thrombosis (blood clot in the leg causing pain, redness or swelling)

If you notice any undesirable effects not mentioned in this leaflet, please inform your doctor or pharmacist of them.

HOW SHOULD LIPANTHYL 160 mg film-coated tablet be STORED?

Store at a temperature below 30° C.

This medicine is sensitive to humidity and should be stored in its outer wrapping.

Do not leave within reach or sight of children.

Do not use after the expiry date printed on the box.

The latest date on which this leaflet was approved is June 2010.