

LIPANTHYL® 200M

FENOFIBRATE MICRONISÉ

PRODUCT IDENTIFICATION

NAME

LIPANTHYL® 200 micronised, capsule.
Fenofibrate

COMPOSITION PER CAPSULE

Fenofibrate (INN): 200 mg.
Sodium lauryl sulphate, lactose, pregelatinised starch, crospovidone, magnesium stearate.

Capsule shell: gelatin, titanium dioxide (E171), iron oxide (E172), erythrosin (E127).

PHARMACEUTICAL FORMULATION

Hard capsule.

PHARMACO-THERAPEUTIC CLASS

SERUM LIPID REDUCING AGENTS/CHOLESTEROL AND TRIGLYCERIDE REDUCERS/FIBRATES.

MANUFACTURER

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

THERAPEUTIC INDICATIONS

This medication is recommended for the treatment of hypercholesterolaemia (abnormally elevated levels of cholesterol in the blood) and/or hypertriglyceridaemia (abnormally elevated levels of triglycerides - fats - in the blood) in adults, when the response to an appropriate and correctly observed diet is inadequate.

WARNING !

CASES WHERE THIS MEDICATION SHOULD NOT BE USED

This medication SHOULD NOT BE USED in the following cases:

- hepatic (liver) impairment,
- renal impairment,
- in children,
- known allergy to fenofibrate or to one of the excipients,
- known phototoxic or photoallergic reactions (skin reactions following exposure to the sun or to artificial UV light) in the course of a treatment with fenofibrate or with a structurally-related substance, in particular ketoprofen (anti-inflammatory drug).

SPECIAL WARNINGS

- Inform your doctor immediately if you experience muscle pains (see "Undesirable and discomforting effects" section).
- Liver tests will be performed before the treatment starts. These will be repeated regularly during the first year of treatment,
- Due to the presence of lactose, this product is contra-indicated in case of congenital galactosemia, glucose and/or galactose malabsorption syndrome, or lactase deficiency (rare metabolic disease).

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

PRECAUTIONS FOR USE

Taking this medication does not replace the diet you are on; its regular continuation is still essential. Regular blood tests are required.

DRUG INTERACTIONS AND OTHER INTERACTIONS

TO AVOID POSSIBLE REACTIONS WITH OTHER DRUGS, PLEASE INFORM YOUR DOCTOR OF ANY OTHER PRODUCTS YOU ARE CURRENTLY TAKING AND DO NOT HESITATE TO TELL YOUR DOCTOR OR YOUR PHARMACIST ABOUT ANY ABNORMAL SIGNS YOU NOTICE DURING THE TREATMENT, particularly if you are taking an anticoagulant or another drug to treat high cholesterol (another fibrate, statin).

PREGNANCY - BREAST-FEEDING

It is unadvisable to take this medication during pregnancy. If you discover that you are pregnant and have been taking this medication, please stop the treatment immediately and consult your doctor.

As no information is available concerning the transfer of this medication in breast milk, this treatment is not advisable during breast-feeding.

HOW TO USE THIS MEDICATION

DOSAGE

The dosage is set at 1 capsule daily.

IN ALL CASES, FOLLOW EXACTLY THE PRESCRIPTION GIVEN BY YOUR DOCTOR.

ADMINISTRATION METHOD AND ROUTE

Oral route.

FREQUENCY AND TIME AT WHICH YOU SHOULD TAKE THIS MEDICATION

The treatment is to be taken as 1 capsule daily, during a meal, as noted in your doctor's prescription.

TREATMENT DURATION

In combination with dieting this medication constitutes long-term symptomatic treatment that is regularly monitored.

To use this medication correctly it is very important that you undergo regular medical check-ups.

UNDESIRABLE AND DISCOMFORTING EFFECTS

LIKE ANY ACTIVE PRODUCT, THIS MEDICATION CAN, IN CERTAIN PERSONS, HAVE UNPLEASANT SIDE-EFFECTS WHICH CAUSE A GREATER OR LESSER DEGREE OF DISCOMFORT.

These effects occur rarely and are benign:

- gastrointestinal disorders such as digestion difficulties,
- allergic or photosensitivity skin reactions such as eruptions, or itching (during an exposure to the sun or to artificial UV light). In some cases, even after several months of use without complication, a skin reaction may appear on skin areas exposed to the sun or to artificial UV light (sunbeds),
- transiently elevated transaminases (liver enzymes),
- gallstones,
- pneumopathies,
- muscle pains (with occasionally an increase in muscle enzymes).

If you feel any muscle pain, painful muscle sensitivity or muscle weakness, contact your doctor immediately as muscle disorders can in rare cases be serious.

REPORT ANY UNDESIRABLE OR DISCOMFORTING EFFECTS NOT MENTIONED IN THIS DOCUMENT TO YOUR DOCTOR OR YOUR PHARMACIST.

STORAGE

DO NOT EXCEED THE EXPIRY DATE NOTED ON THE PACKET

SPECIAL STORAGE CONDITIONS

Keep in a dry place, below 30 °C.

REVISION DATE OF PACKAGE INSERT

February 2010



606720A

Laboratoires
Fournier



Recipharm		SERVICE PACKAGING		COULEURS		DATE
BAT réalisé par: D.Margueritte				NOIR		NOM (REGULATORY PERSON)
DÉSIGNATION DE L'ARTICLE		CODE ET VERSION				VISA
PROS LIPANTHYL M 200 MG 30 GEL JO KW		606720A				
DIMENSIONS	DATE	DOCUMENT N°:	MAQ.	EXÉ.		
170 x 214	16/09/10	1	1			