LIPANTHYL PENTA 145 mg tablet

1. NAME OF THE MEDICINAL PRODUCT
LIPANTHYL® PENTA 145, Film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One film-coated tablet contains 145 mg fenofibrate (nanoparticles).

3. PHARMACEUTICAL FORM
Film-coated tablets

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
Fenofibrate enhances oral anticoagulant effect and may be used in patients with renal insufficiency (see contraindications).

4.2. Posology and method of administration
In combination with diet, this medicinal product constitutes a long-term treatment, and smoking.

4.3. Contraindications
LIPANTHYL® PENTA 145 is contraindicated in children, during pregnancy and lactation, in patients with known hypersensitivity (excluding lapses in catarrhal and urticarial symptoms). It is not recommended in patients with severe hepatic insufficiency caused by blockage of the common bile duct, choledocholithiasis or hyperlipidaemia. It is also contraindicated in patients with renal insufficiency (see Special warnings and precautions for use).

4.4. Special warnings and precautions for use
Muscle toxicity should be suspected in patients with renal or hepatic impairment, and in patients with a history of myopathy and/or rhabdomyolysis, and in patients with hypertriglyceridaemia (see Special warnings and precautions for use).

4.5. Interactions with other medicinal products and other forms of interaction
Concomitant use of HMG-CoA reductase inhibitors and other fibrates is not recommended due to the risk of rhabdomyolysis. The concomitant use of fenofibrate with astatin and/or another fibrateshould bereserved topatients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease. This combination therapy should be used with caution and patients should be monitored closely for signs of muscle toxicity.

4.6. Pregnancy and lactation
This medicinal product contains sucrose, therefore patients with rare hereditary malabsorption should not take this medicine.

4.7. Effects on the ability to drive and use machines
Driving and use of machines should not be impaired by fenofibrate therapy.

4.8. Undesirable effects

5. PHARMACOLOGICAL PROPERTIES
Fenofibrate is a fibrate with a weak inhibitory effect on CYP2C19, CYP2A6, and CYP3A4. Its metabolism is rapid, with a half-life of approximately 9 hours. Fenofibrate is primarily excreted in the urine, with a small fraction excreted in the faeces.

6. PRESENTATION
White, oblong, film-coated tablets engraved "145" on one side and "Fournier logo" on the other side.

7. STABILITY
LIPANTHYL® PENTA 145, film-coated tablets should not be taken in patients allergic to soya bean lecithin or related products due to the risk of hypersensitivity reactions.

8. OVERDOSAGE
Some severe cases of reversible renal function impairment have been reported during concurrent administration of fenofibrate and cyclosporin. The renal function of these patients must therefore be closely monitored and the treatment with fenofibrate stopped in the case of severe alteration of laboratory parameters.

9. MARKETING AUTHORISATION HOLDER
Recipharm

10. TRAINEES AND TRAINING INSTRUCTORS

11. PACKAGING
LIPANTHYL® PENTA 145, film-coated tablets are available in blister packs of 145 mg in quantities of 145 mg in quantities of 28 tablets.

12. DATE
12/10/20

13. VISA

14. CODE ET VERSION

15. SERVICE PACKAGING

16. MENUS (HASSELDIA PABLO)

17. CODE DE PRODUIT

18. DATE DE FIN DE LA VALIDITE

19. IDENTITE DU PRODUIT

20. N° DE LA DEPARTEMENTAL DISCLAIMER OF LIABILITY

21. REMARKS
**Maximum plasma concentrations (Cmax) occur within 2 to 5 hours.**

**Cardiovascular system**

- Lipid-lowering (ludomic agent, deep vein thrombosis)
- Blood and lymphatic system disorders
- Rare: haematological and blood disorders

**Absorption:**

- Fenofibrate is a bile acid derivative whose lipophilic modifying effects reported in humans are mediated via activation of PPARα, a nuclear receptor (type alpha 1)
- Through activation of PPARα, fenofibrate increases the lipolysis and catabolism of abnormal triglyceride-rich lipoprotein from plasma by activating lipoprotein lipase and reducing production of apolipoprotein B and triglycerides
- Activation of PPARα also induces an increase in the synthesis of apolipoprotein A-1 in HDL
- The above stated effects of fenofibrate on lipoproteins lead to a reduction in very low-density lipoproteins (VLDL) containing, apolipoprotein B and an increase in the high density lipoprotein fraction (HDL) containing, apoprotein of HDL
- In addition, through modulation of the synthesis and the catabolism of HDL fraction, fenofibrate increases the HDL clearance and reduces small dense LDL, the levels of which are elevated in the atherogenic lipoprotein phenotype, a common disorder in patients at risk for coronary heart disease
- During clinical trials with fenofibrate, total cholesterol was reduced by 30 to 40% and LDL cholesterol by 20 to 30% in Hypercholesterolemic patients with or without hypertriglyceridemia, including secondary hypertriglyceridemia (type 2 diabetic hypertriglyceridemia patients) and or non-familial hypercholesterolemia
- In hypercholesterolemic patients, where LDL cholesterol levels are reduced by 20% to 30% and triglycerides by 40% to 55%, HDL cholesterol was increased by 10 to 30%.

**Contraindications**

- Patients with severe hepatic disease
- Those with a history of gallbladder disease
- Patients with a history of history or at increased risk for gallbladder disease

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