

# [Fenofibrate]

DYSLIPIDEMIA

## GENERIC FORM OF LIPANTHYL®

### STRENGTHS AND PHARMACEUTICAL FORMS:

130 mg, micronized tablet in capsules  
145 mg, nanonized tablet  
160 mg, tablet  
67 – 200 mg, micronized pellets in capsules

### PHARMACOLOGICAL AND THERAPEUTIC PROPERTIES:

Fenofibrate is a fibric acid derivative whose lipid modifying effects reported in humans are mediated via activation of Peroxisome Proliferator Activated Receptor type alpha (PPAR $\alpha$ ).

It is indicated in hypercholesterolaemia and hypertriglyceridaemia alone or combined (types IIa, IIb, IV dyslipidaemias, as well as types III and V dyslipidaemias although only a few patients have been treated during clinical trials) in patients unresponsive to dietary and other non-drug therapeutic measures (e.g. weight reduction or increased physical activity), particularly when there is evidence of associated risk factors.

The treatment of secondary hyperlipoproteinaemias is indicated if the hyperlipoproteinaemia persists despite effective treatment of the underlying disease (e.g. dyslipidaemia in diabetes mellitus).

### CTD DOSSIERS:

**Fenofibrate 145 mg:** comparative bioavailability study with the reference products Tricor® and Lipanthyl®, following a single dose administration, in fed and fasting condition.

**Fenofibrate 67 – 200 mg:** CTD dossier available in Europe

**Fenofibrate 160 mg:** CTD dossier available in Europe

**Fenofibrate 130 mg:** CTD dossier available in the US

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