Fenofibrate 160 , 200 & 267 mg

Capsule

CARDIO METABOLIC

ATHENA PHARMACEUTIQUES

Fenofibrate micronized formulation for a once-a-day administration

Key features

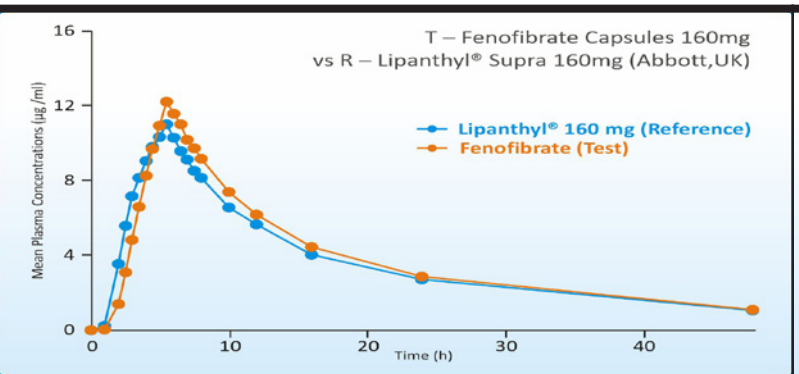
- Micronized formulation results improving patient's compliance, daily dose reduction whilst ensuring an optimal drug efficacy.

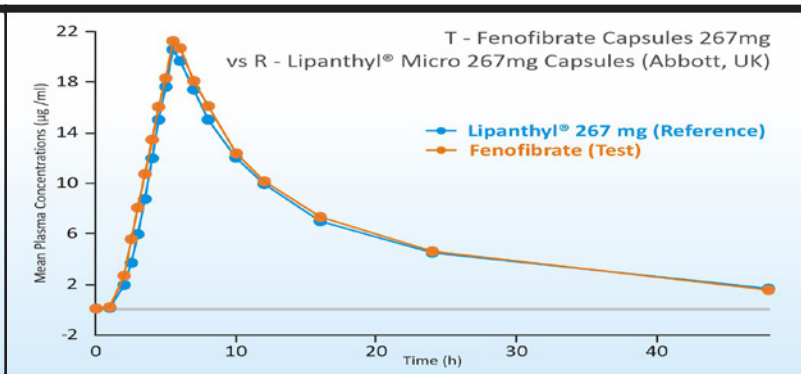
Competitive advantages

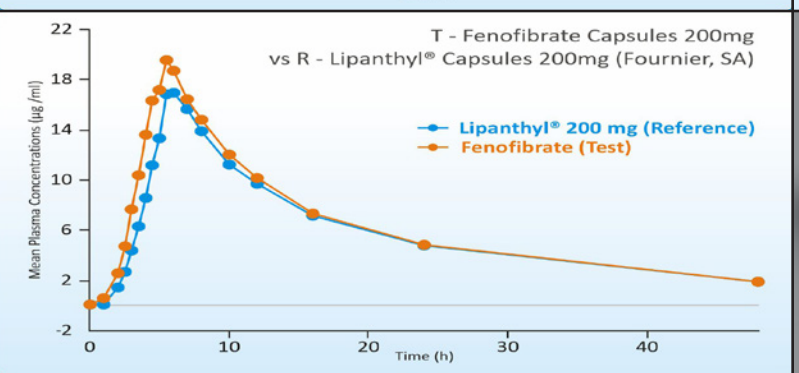
- Fenofibrate is a third generation fibric acid practically insoluble in water, making it challenging to consistently achieve therapeutic levels[1,2]. Micronization technology dramatically improves the dissolution rate-limited gastrointestinal absorption.

Regulatory status

- INN: Fenofibrate
- ATC Code: C10AB05
- CAS registry number: 49562-28-9
- Reference compound: LIPANTHYL® Capsule, Abbott.
- BioEq. study
  - Patient population: 25 (160 mg), 20 (200 mg) & 25 (267 mg) male & female healthy volunteers.
  - Methodology: Randomized, 2-way crossover, fed study.
  - Reference product: LIPANTHYL® 160 mg supra, LIPANTHYL® 200 mg capsule & LIPANTHYL® 267 mg micro-capsule, Abbott UK & France (200 mg).
- Zone IV stability data available.
- CTD dossier available.







Fenofibrate 160, 200 & 267 mg

Capsule

CARDIO METABOLIC

Information at a glance

- Commercial batch size (million doses): 160 mg: 1 225 | 200 mg: 0.975 | 267 mg: 0.725
- Dossier Batch size (million doses): 160 mg: 0.625 | 200 mg: 0.375 | 267 mg: 0.125
- Shelf-life: 160 mg: 2 years | 200 & 267 mg: 3 years
- Storage conditions: Store at 25 °C; excursions permitted to 15-30 °C - Protect from moisture
- Pack info: clear transparent PVC-Alu. blister
- Tablet weight / strength: 160 mg: 240 mg | 200 mg: 300 mg | 267 mg: 400 mg

Market highlights

- Hyperlipidaemia is the most predominant risk factor associated with the high mortality rate in patients suffering from coronary artery disease[3].
- Lipid lowering drugs market was valued $20.6 billion by 2019 and is expected to grow at a CAGR of 2.6% over the period 2020-2027[4].

Competitors' landscape

- Fibrates (LIPUR®/gemfibrozil, ATROMID®/clofibrate), ezetimibe (ZETIA®), HMG-CoA Reductase inhibitors (LESCOL®/fluvastatin, PRAVACHOL®/pravastatin, ZOCOR®/simvastatin, LIPITOR®/atorvastatin, CRESTOR®/rosuvastatin), bile acid sequestrants (QUESTRAN®/cholestyramine).

REFERENCES

1. Vogt M et al Eur J Pharm Biopharm 68(2):283-288 (2008)
2. Ling H et al Cardio Res 4(2):47-55 (2013)
3. Miller M et al Circulation Vol123 Issue 20 2292-2333 (2011)
4. Lipid Lowering Drug market, Atlantic Market Research (2019)

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Key numbers

- **Lipid-lowering drug market: $20.6 billion in 2019**
- **CAGR 2020-2027: 2.6%**

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