



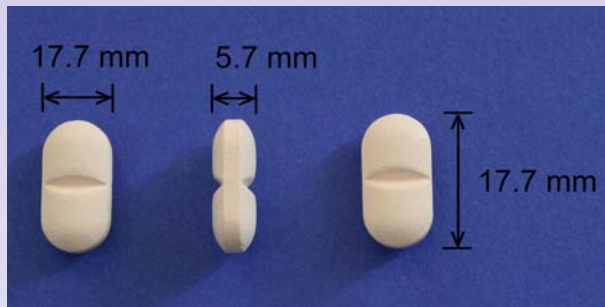
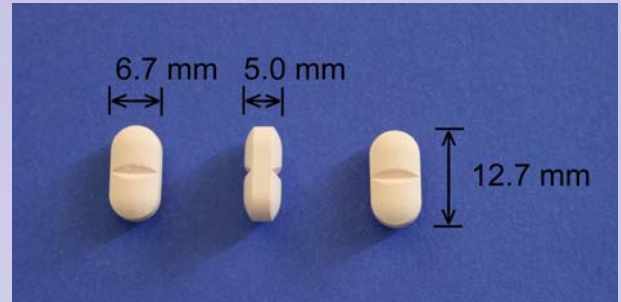
Levofloxacin Hemihydrate Film-Coated Tablets

Therapeutic indication: Bacterial infection

250 mg Film-Coated Tablets

One film-coated tablet contains:
256.23 mg Levofloxacin $\frac{1}{2}$ H₂O
(250 mg Levofloxacin)

Weight: 360 mg



500 mg Film-Coated Tablets

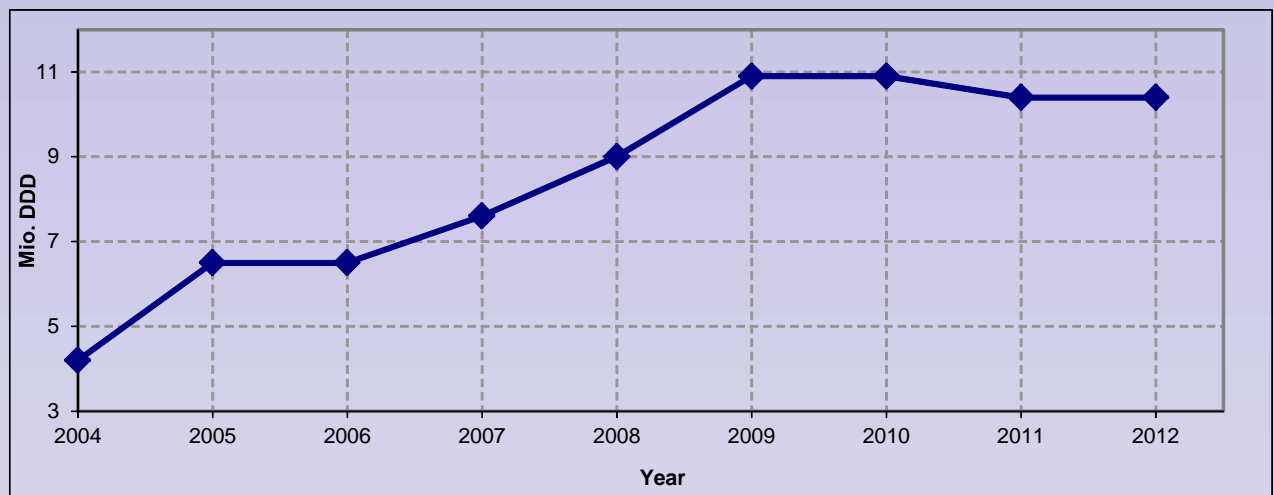
One film-coated tablet contains:
512.46 mg Levofloxacin $\frac{1}{2}$ H₂O
(500 mg Levofloxacin)

Weight: 720 mg



We expressly point out that these dossiers or marketing authorisations cannot be used in countries where corresponding medicinal products or the application of such products are protected by patent.

Prescriptions (in Mio Defined Daily Doses) of Levofloxacin in Germany



Source: Schwabe, Paffrath Arzneiverordnungsreport

Levofloxacin is a synthetic antibacterial agent of the fluoroquinolone class brought to market in nearly all European countries.

Product advantages: New High Quality IIP-EU Development-Line

- Dossiers for 250 and 500 mg available
- Authorisations accomplished in more than 10 EU countries with additional non-EU countries
- API allows an early launch in countries with process patents
- 250 mg and 500 mg tablets show good divisibility
- Colour and shape of the tablets are comparable to reference product
- Production at a cGMP compliant contract manufacturer in a European country
- High manufacturing capacities for sales peaks
- Competitive prices for the contract manufacturing
- Economic manufacturing through homologous dosage forms
- BE study at hand
- Identity of the reference product has been proven for countries: FR, AT, BE, DK, FI, DE, IE, IT, LV, NL, PT, ES, UK
- Second API source for more flexibility qualified
- Samples and exposé with scientific data available upon request



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