



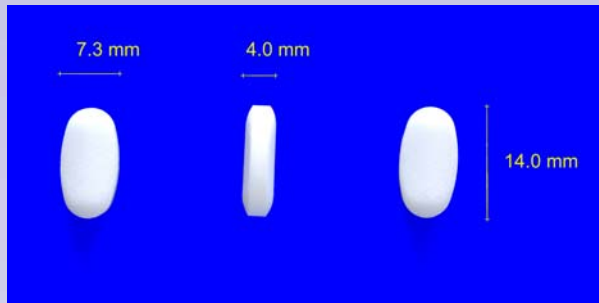
Sodium Valproate / Valproic Acid

Prolonged-Release Film-Coated Tablets

IIP-EU-Development Line



Therapeutic indication: Epilepsy, Bipolar disorder

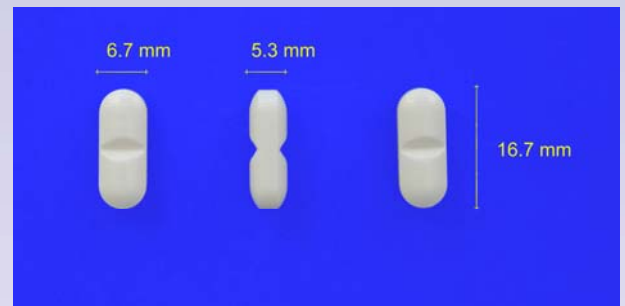


200 mg Prolonged-Release Film-Coated Tablets

One prolonged-release film-coated tablet contains: 133.2 mg sodium valproate and 58.0 mg valproic acid (corresponding to 200 mg sodium valproate)
Weight: 303 mg

300 mg Prolonged-Release Film-Coated Tablets

One prolonged-release film-coated tablet contains: 199.8 mg sodium valproate and 87.0 mg valproic acid (corresponding to 300 mg sodium valproate)
Weight: 451 mg



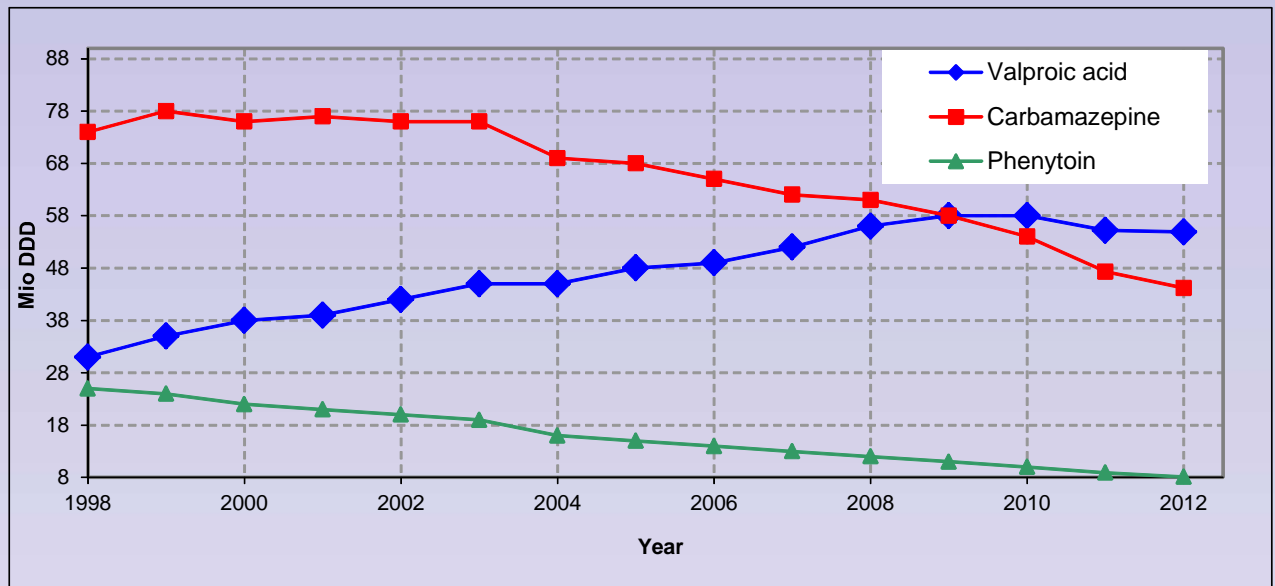
500 mg Prolonged-Release Film-Coated Tablets

One prolonged-release film-coated tablet contains: 333.0 mg sodium valproate and 145.0 mg valproic acid (corresponding to 500 mg Sodium valproate)
Weight: 745 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 of Antiepileptics (German Market)



Source: Schwabe, Paffrath Arzneiverordnungsreport

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

- Marketing Authorisations and Dossiers, respectively, for 300 and 500 mg available
- Dossier for 200 mg available
- Marketing Authorizations granted in 13 European countries
- **cGMP compliant, European API manufacturer / EU-development**
- APIs with CEP incorporated in the dossiers
- **cGMP compliant, European contract manufacturer with high manufacturing capacities for sale peaks**
- Competitive prices, high batch sizes
- 300 and 500 mg tablets show good divisibility
- Colour and shape of the tablets is comparable to reference products
- Stability data for pilot scale batches and for production batches available
- Packaging in tubes or aluminium / aluminium blisters possible
- European BE studies for 300 and 500 mg, clinical centre with EU Audit and bio-analytical centre with ISO certificate
- Identity of the reference product has been proven for countries like: AT, BE, CH, CZ, DE, FR, IT, NL, UK, ZA
- Oral Solution, solution for injection, gastro-resistant tablets and sodium valproate/valproic acid prolonged-release film-coated tablets ⇒ Complete package for Sodium Valproate /Valproic acid available
- Samples and exposé with scientific data available upon request



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