

Pharmaceutical Product

OPIPRAMOL DIHYDROCHLORIDE film-coated tablets

Active Pharmaceutical Ingredient	Opipramol Dihydrochloride
Indication	Generalized anxiety, somatoform disturbances
ATC-Code	N06AA05
Product USPs	– Good divisibility of the tablets – Sugar- and lactose-free dosage forms
Reference Product	Insidon® / Novartis
Strength	50 mg and 100 mg
Dosage Form	Film-coated tablets (FCT), yellow, biconvex, 50 mg: without break mark 100 mg: double sided break mark Odour: nearly odourless
Batch Sizes	50 mg: batch size 130 kg, corr. to 1,000,000 FCT batch size 780 kg, corr. to 6,000,000 FCT 100 mg: batch size 260 kg, corr. to 1,000,000 FCT
Primary Packaging	Blister Alu-PVC with 10 FCT
Secondary Pack Size	50 mg: boxes of 20, 60, 90, 120 FCT 100 mg: boxes of 20, 60, 90, 120 FCT
Manufacturer	Aenova Site Dragenopharm Apotheker Püschl GmbH (DE)
Stability Data (ICH)	CZ II on 2 batches per strength for 5 years (pilot) CZ II + IVa on 3 batches 50 mg and 3 batches 100 mg for 5 years Shelf life: 5 years
Status Dossier	Modules 2-5 in EU-CTD available BE study of Opipramol 50 mg Bio-waiver for Opipramol 100 mg