

Pharmaceutical Product

GINKGO (GINKGO BILOBA) film-coated tablets

Active Pharmaceutical Ingredient	<i>Ginkgo biloba</i>	
Indication	Improvement of brain deficiency	
ATC-Code	N06DP01	
Reference Product	Tebonin® (Dr. Willmar Schwabe GmbH & Co. KG)	
Strength	40 mg, 80 mg, 120 mg and 240 mg	
Dosage Form	Film-coated tablets (FCT)	
Batch Size	40 mg:	batch size 1,320,000 FCT
	80 mg:	batch size 200,000 and 660,000 FCT
	120 mg:	batch size 400,000 and 600,000 FCT
	240 mg:	batch size 400,000 and 600,000 FCT
Primary Packaging	Blister Alu-PVC/PVDC	
Secondary Pack Size	Boxes of 30, 60, 90 and 120 FCT	
Manufacturer	Aenova Site Dragenopharm Apotheker Püschl GmbH (DE) Packaging: Aenova Site Swiss Caps GmbH (DE)	
Stability Data (ICH)	CZ II on 2 batches for 60 months	
	CZ II on 2 batches (start 2014)	
	CZ II on 1 batch (start 2017)	
	Shelf-life: 5 years Do not store above 30°C	
Status Dossier	Dossier in EU-CTD available	