

Pharmaceutical Product

ARTICHOKE (CYNARA SCOLYMUS) sugar-coated tablets

Active Pharmaceutical Ingredient	<i>Cynara scolymus</i>
Indication	For the symptomatic relief of digestive disorders, such as dyspepsia with a sensation of fullness, bloating and flatulence
Strength	300 mg
Dosage Form	Sugar-coated tablets (SCT)
Batch Size	900,000 SCT
Primary Packaging	Blister Alu-PVC/PVDC
Secondary Pack Size	Boxes of 40, 50, 60, 80, 100 and 120 SCT
Manufacturer	Bulk: Aenova Site Dragenopharm Apotheker Püschl GmbH (DE) Packaging: Aenova Site Swiss Caps GmbH (DE)
Stability Data (ICH)	CZ II on 2 batches for 3 years CZ II on 2 batches for 2 years (still ongoing) Shelf life: 3 years Do not store above 30°C
Status Dossier	Dossier in EU-CTD available Product registered in Germany (Galle-Dragee with Artichocke) and UK (DigestAid coated tablets), complies with HMPC-Monograph for Cyanara scolymus L., folium (Artichoke leaf)