

Pharmaceutical Product

MILK THISTLE (SILYBUM MARIANUM L.) soft gelatin capsules

Active Pharmaceutical Ingredient	<i>Silybum marianum L.</i>
Indication	Relief of digestive disorders, sensation of fullness and indigestion and to support the liver function
Strength	200 mg
Dosage Form	Soft gelatin capsule (SGC)
Batch Size	1,000,000 SGC
Primary Packaging	Blister Alu-PVC/PVDC
Secondary Pack Size	Boxes of 20, 24, 40, 48, 60, 80, 90, 100 and 120 SGC
Manufacturer	Bulk: Aenova Site Swiss Caps AG (CH) & Swisscaps Romania S.r.l. (RO) Packaging: Aenova Site Swiss Caps GmbH (DE)
Stability Data (ICH)	CZ II on 3 batches for 3 years Shelf life: 3 years Do not store above 25°C
Status Dossier	Dossier in EU-CTD available Product registered in Germany (Mariendistel Kapsel); complies with HMPC-Monograph for <i>Silybum marianum, fructus</i>