

Pharmaceutical Product

VALERIAN (VALERIAN OFFICINALIS) sugar-coated tablets

Active Pharmaceutical Ingredient	<i>Valerian officinalis L.</i>
Indication	Relief of mild symptoms of mental stress and to aid sleep
Strength	150 mg
Dosage Form	Sugar-coated tablets (SCT)
Batch Size	2,000,000 SCT
Primary Packaging	Blister Alu-PVC/PVDC
Secondary Pack Size	Boxes of 30, 40, 90 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 18 months (still ongoing) Shelf life: 3 years Do not store above 30°C
Status Dossier	Dossier in EU-CTD available Product registered in Germany (Nachtruhe Baldrian Schlaf-Dragees N); complies with HMPC monograph for <i>Valerian officinalis L.</i> , radix (Valerian root)