

Pharmaceutical Product

VALERIAN (VALERIAN OFFICINALIS) / HOP (HUMULUS LUPULUS) sugar-coated tablets

Active Pharmaceutical Ingredient	<i>Valeriana officinalis L.</i> and <i>Humulus lupulus L.</i>
Indication	Relief of mild symptoms of mental stress and aid to sleep
Strength	187.5 mg / 45 mg
Dosage Form	Sugar-coated tablets (SCT)
Batch Size	1,600,000 SCT
Primary Packaging	Blister Alu-PVC/PVDC
Secondary Pack Size	Boxes of 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 25°C
Status Dossier	Dossier in EU-CTD available Product registered in Germany (Beruhigungs Dragee mit Baldrian Hopfen) Complies with HMPC-Monograph for <i>Valeriana officinalis L.</i> , radix and <i>Humulus lupulus L.</i> , flos