

Pharmaceutical Product

## BEARBERRY LEAF (ARCTOSTAPHYLOS UVA-URSI) film-coated tablets

<b>Active Pharmaceutical Ingredient</b>	<i>Arctostaphylos uva-ursi</i>
<b>Indication</b>	Inflammatory diseases of the efferent urinary tracts
<b>ATC-Code</b>	G04BX
<b>Strength</b>	105 mg Hydrochinon derivates corresponding to 425.25 mg – 519.75 mg dried extract of bearberry leaf (2.5 – 4.5:1), ES: water
<b>Dosage Form</b>	Film-coated tablets (FCT)
<b>Batch Size</b>	672,000 FCT
<b>Primary Packaging</b>	Blister Alu-PVC/PVDC
<b>Secondary Pack Size</b>	Boxes of 60 FCT
<b>Manufacturer</b>	Bulk: Aenova Site Dragenopharm Apotheker Püschl GmbH (DE) Packaging: Aenova Site Swiss Caps GmbH (DE)
<b>Stability Data (ICH)</b>	CZ II on 8 batches (5 TW; 3 DRPH) for 36 months Shelf life: 3 years Do not store above 25°C
<b>Status Dossier</b>	Dossier in EU-CTD format available