

**Initial Submission** Ribomustin 100 MG (Onctec pharma produkton GMBH site)

**Reg No.** 1C 57/58 (NC)

**Approval date** 3 Jun 2015

Variation submission

<b>Application number</b>	<b>Scope</b>	<b>Approval date</b>	<b>Product Information affected</b>	<b>Summary</b>
15069/61 (N)	<b>MiV-PA2</b> : Change of product labeling (in accordance to country specific labeling requirement)	18 Apr 2018	PIL	
15041/60 (N)	<b>MaV 1</b> : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	17 Nov 2017		