

Initial Submission Ribomustin 100 MG

Reg No. 1C 55/58 (NC)

Approval date 3 Jun 2015

Variation submission

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