

Initial Submission BELKYRA Reg No. 1C 15031/61 (NC) Approval date 21 May 18

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15037/62(N)	<b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)	11 Mar 2019	Patient information leaflet	
15084/61 (N)	<b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)	7 Dec 2018	Patient information leaflet	