

Initial Submission Prezista 400 mg

Reg No. 1C 22/56 (N)

Approval date 24 Jan 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
i15099/61(N)	MaV-2 Change of content of product labeling	30 Jan 2019	Patient information leaflet	
i15155/61 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	7 Dec 2018	Labeling	
i15011/62 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	21 May 2019		