

Initial Submission Ibrance (Capsules 100 mg)

Reg No. 1C 69/60 (NC)

Approval date 26 Sep 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15062/61 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	19 Jan 2018	Patient information leaflet	
15011/61 (N)	MaV1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	5 Oct 2018	Patient information leaflet	
15021/61 (N)	MiV-PA 30 Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product	1 Oct 2018		
15181/61 (N)	MaV-15 Extension of shelf-life of the drug product	14 Feb 2019		