

Initial Submission Xarator (Tablets 80 mg)

Reg No. 1C 36/60 (N)

Approval date 8 May 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15008/61 (N)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product MaV-2 Change of content of product labeling MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	17 Sep 2018	Patient information leaflet Summary of Product Characteristics	
15048/61 (N)	MiV-PA8 Change of the specification of drug substance	31 Oct 2018		
15057/61 (N)	MiV-PA24 Change of release and shelf-life specifications of the drug product	6 Jun 2019		
15006/62 (N)	MaV-2 Change of content of product labeling	26 Dec 2018	Patient information leaflet Summary of Product Characteristics	

