

Initial Submission Xarator (Tablets 10 mg)

Reg No. 1C 33/60 (N)

Approval date 8 May 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15008/61 (N)	<b>MaV-1</b> Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product <b>MaV-2</b> Change of content of product labeling <b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)	17 Sep 2018	Patient information leaflet Summary of Product Characteristics	
15048/61 (N)	<b>MiV-PA8</b> Change of the specification of drug substance	31 Oct 2018		
15057/61 (N)	<b>MiV-PA24</b> Change of release and shelf-life specifications of the drug product	6 Jun 2019		
15006/62 (N)	<b>MaV-2</b> Change of content of product labeling	26 Dec 2018	Patient information leaflet Summary of Product Characteristics	
15056/62 (N)	<b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)	21 Mar 2019	Label	