

Initial Submission Vokanamet 150 mg/500 mg

Reg No. 2C 15077/63 (NC)

Approval date 3 Apr 2020

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15098/62 (NB)	MaV 2 : Change of content of product labeling	5 Mar 2020	PIL User testing	
15160/61 (N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	4 Mar 2020	SmPC , PIL	
15162/61 (N)	Non-AVG			
15160/61 (N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product		Patient Information Leaflet and Summary of Product Characteristics	
15089/61 (N)	Non-AVG MiV-N4 : Change of the name or address (for example: postal code, street name) of the manufacturer of drug product , MaV-15 Extension of shelf-life of the drug product			
15144/61 (N)	non-AVG	30 Nov 2018	Summary of Product Characteristics	