

Initial Submission Amitiza (8 mcg)

Reg No. 1C 15057/61 (NC)

Approval date 22 Jul 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15068/62 (N)	MaV 2 Change of content of product labeling	5 Jul 2019	Summary of Product Characteristics	
15021/62 (N)	non-AVG	15 Feb 2019	Patient Information Leaflet	