

Initial Submission esmya 5 mg

Reg No. 1C 15047/61 (NC)

Approval date 25 Jun 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15004/62 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	9 Jul 2019	Patient Information Leaflet	
15139/61 (N)	MiV-PA1 : Change of drug product name	6 Nov 2018	Label , Patient Information Leaflet, Package insert and Summary of Product Characteristics	