

Initial Submission Uptarvi 400 mcg

Reg No. 1C 15040/61 (NC)

Approval date 26 Jun 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15121/61 (N)	Non AVG	7 Nov 2018	SPC	
15120/61 (N)	MiV-PA2 : Change of product labeling (in accordance to country specific labeling requirement)	28 Sep 2018	Labeling	
15119/61 (N)	MaV 4 : Addition or replacement of the manufacturing site of the drug product MiV-PA 29 : Addition or replacement of a manufacturer for secondary packaging	26 Oct 2018		
15118/61 (N)	MaV 2 : Change of content of product labeling	25 Oct 2018	PIL	