

Initial Submission ADVATE 500 IU

Reg No. 1C 15038/63 (NBC)

Approval date 22 Jan 2020

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15100/61 (NB)	MiV-PA2 Change of product labeling (in accordance to country Specific labeling requirement)	30 Oct 2018	label	
15096/61 (NB)	Non-AVG	30 Oct 2018		