Initial Submission Acarizax

Reg No. 2C 15020/61 (NBC)

Approval date 28 Mar 2018

Register submission

Application number	Scope	Approval date	Product Information affected	Summary
15029/62 (NB)	non-AVG	30 Apr 2019		
15025/62 (NB)	AVG MaV PA3 Addition or replacement of the company or party responsible for batch release	28 May 2019		
15027/62 (NB)	non-AVG	10 May 2019		
15026/62 (NB)	non-AVG	22 Jul 2019		

Application number	Scope	Approval date	Product Information affected	Summary
15024/62 (NB)	MiV-N 4 Change of the name or	22 Aug 2019		
	address (for example: postal			
	code, street name) of the			
	manufacturer of drug product			
	MiV-N 6 Change of the name			
	and/or address (for example:			
	postal code, street name) of a			
	manufacturer of the drug			
	substance			
15101/62 (NB)	MiV-PA 2	22 Aug 2019	Patient information leaflet	
	Change of product labeling (in			
	accordance to country specific			
	labeling requirement)			