

Initial Submission

Zerbaxa

Reg No. 2C 18/60 (NC)

Approval date

16 Jun 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15046/61 (N)	<b>MiV-N6</b> : Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance	4 Sep 2018		
15032/61 (N)	<b>Non AVG</b>	4 Sep 2018		
15067/61 (N)	<b>MiV-PA2</b> : Change of product labeling (in accordance to country specific labeling requirement)	10 Feb 2018	PIL, Labeling	
15030/60 (N)	<b>Non AVG</b>	5 Feb 2018		
15016/60 (N)	<b>MiV-PA2</b> : Change of product labeling (in accordance to country specific labeling requirement)	1 Sep 2017	PIL	