

Initial Submission ultracet

Reg No. 2C 26/51 (N)

Approval date 3 Sep 2008

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
i15072/62 (N)	non-AVG	24 Apr 2019	Patient Information Leaflet and Summary of Product Characteristics	
i15088/61 (N)	MaV-2 Change of content of product labeling	31 Oct 2018	Patient Information Leaflet and Summary of Product Characteristics	
i15087/61 (N)	MiV-PA19 Change of in-process controls applied during the manufacture of the drug product (including tightening and addition of new in- process test)	12 Oct 2018	label	
i15005/61 (N)	MiV-PA19 Change of in-process controls applied during the manufacture of	11 Oct 2018		

	the drug product (including tightening and addition of new in- process test)			
i15081/61 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	30 Aug 2018	label	
i15056/61 (N)	MiV-N6 Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance	10 Jul 2018		
i15004/61 (N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	25 Apr 2018	label	
i15057/60(N)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	17 Jan 2018	label	

