

Initial Submission Imbruvica (Cilag site)

Reg No. 1C 73/60 (NC)

Approval date 2 Nov 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15171/62 (N)	MiV-PA 2 Change of product labeling (in accordance to country specific labeling requirement)	5 Sep 19	PIL	
15167/61 (N)	MaV 6 Change of the specification drug substance and/or drug product [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	23 Aug 2019		
15099/62 (N)	MaV 1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	25 Jun 2019	PIL, SmPC	

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15140/61 (N)	MaV 1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	11 Mar 2019	PIL	
15082/62 (N)	Non AVG	24 Apr 2019	PIL	
15109/61 (N)	Non AVG	14 Feb 2019		
15145/61 (N)	MaV 2 : Change of content of product labeling	8 Feb 2019	PIL, Labeling	
15050/60 (N)	MaV 1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	13 Jul 2018	PIL, SmPC	