

Initial Submission ZAFATEK

Reg No. 1C 15001/61 (NC)

Approval date 17 Jan 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15095/61(N)	MiV-PA3 Addition or replacement of the company or party responsible for batch release	7 Nov 2018		
15012/61 (N)	MaV-4 Addition or replacement of the manufacturing site of the drug product	7 Nov 2018		
15013/61 (N)	MaV-3 Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	20 Sep 2018		