

Initial Submission BERLONTIN 300 เบอร์ลอนทิน 300

Reg No. 1A 29/59 (NG)

Approval date 4 Aug 2016

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15038/60 (NG)	MiV-N9 Change of release and shelf-life specifications of the drug product and/or drug substance and/or excipient, following the updates in the compendium	16 Jan 2018 24		
15045/61 (NG)	MaV-3 Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	28 Jan 2019		
15077/61(NG)	Non-AVG	2 Aug 2018		
15165/61 (NG)	Non-AVG	31 Jan 2019		