

Initial Submission praxbind

Reg No. 1C 33/60 (NBC)

Approval date 3 Aug 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15151/61 (NB)	นอกเหนือ AVG	31 Jan 2019		
15007/62 (NB)	MiV-PA2 : Change of product labeling (in accordance to country specific labeling requirement)	23 Jan 2019	Label	
15048/60(NB)	MiV-PA35 : Change of storage conditions of the drug product (Increasing from the current approved storage condition)	13 Jan 2018	Patient Information Leaflet, Package insert and Summary of Product Characteristics	
15158/61 (NB)	นอกเหนือ AVG	30 Nov 2018		
15104/61 (NB)	MaV-2 : Change of content of product labeling	8 Nov 2018	Summary of Product Characteristics	