

Initial Submission Tafinlar (Capsules 50 mg)

Reg No. 1C 29/60 (NC)

Approval date 2 Jun 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15489/63 (N)	MiV-PA2 : Change of product labeling (in accordance to country specific labeling requirement)	30 Nov 2020	เอกสารกำกับยา	
15227/62 (N)	MaV-2 : Change of content of product labeling	10 July 2020	SmPC	
15049/61 (N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	28 Oct 2018	Patient Information Leaflet and Summary of Product Characteristics	
15012/62 (N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	1 May 2019	Patient Information Leaflet and Summary of Product Characteristics	