

Initial Submission Nivestim solution for injection / infusion (480 µg/0.5 ml)

Reg No. 1C 15074/61 (NBS) **Approval date** 8 Oct 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15015/62 (NBS)	MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement)	14 Feb 2019	label	
15164/61 (NBS)	MaV-1 Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	7 Mar 2019	Summary of Product Characteristics	