

**Initial Submission** Nivestim solution for injection / infusion (120 µg/0.2 ml, 300 µg/0.5 ml)

**Reg No.** 1C 15073/61 (NBS)

**Approval date** 8 Oct 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15015/62 (NBS)	<b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)	14 Feb 2019	label	
15164/61 (NBS)	<b>MaV-1</b> 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	