

Initial Submission Alecensa 150 mg hard capsule

Reg No. 1C 54/60 (NC)

Approval date 3 Aug 2017

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15126/61 (N)	MiV-PA3 : Addition or replacement of the company or party responsible for batch release	17 Oct 2018		
15042/60 (N)	MiV-PA6 : Change of in-process controls applied during the manufacture of the drug substance [including tightening and addition of new inprocess test and where European Pharmacopoeial Certificate of Suitability (CEP) is not available]	20 Feb 2018		
15026/60 (N)	MaV 1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	5 Jan 2018	PIL	