

Initial Submission Zytiga (ABIRA TERONE ACETATE) 250 MG TABLETS Reg No. 1C 15018/61 (N) Approval date 28 Mar 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15061/61 (N)	MaV-1 : Change and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product	13 Nov 2018	Patient Information Leaflet and Summary of Product Characteristics	

