

Initial Submission ZYTIGA (ABIRATERONE ACETATE) 250 MG TABLETS

Reg No. 1C 15069/63 (N)

Approval date 10 Mar 2020

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	