

Initial Submission Xultophy

Reg No. 2C 15004/60 (NBC)

Approval date 17 Jan 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15060/61 (NB)	Non-AVG	20 Sep 2018	Summary of Product Characteristics Patient information leaflet Labeling	
15142/61 (NB)	Non-AVG	10 Jan 2019	Patient information leaflet	