

Initial Submission DARUTAB 400 mg

Reg No. 1A 15066/61 (NG)

Approval date 31 Aug 2018

Variation submission

Application number	Scope	Approval date	Product Information affected	Summary
15174/61 (NG)	Non-AVG	27 Dec 2018	Summary of Product Characteristics	
15089/62 (NG)	MiV-PA30 Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product	15 May 2019		