

Steps taken following Prequalification of Lamivudine/Zidovudine 150 mg/300 mg Tablets

Changes	Product information affected	Accepted on
Change in the shelf life of the FPP	SmPC	20 August 2009
Change in the composition of the FPP		22 February 2010
Addition of a breakline to the tablets	PIL, SmPC	12 August 2010
Addition of manufacturer for Lamivudine API		02 August 2011
Change in the specifications of the FPP		03 October 2011
Addition of manufacturer for Zidovudine API		04 February 2013
Change in the name of supplier and manufacturer of FPP	3, 4, 5	02 March 2016
Change in the name of supplier and manufacturer of FPP	3, 4, 5	03 August 2018