

Steps taken following Prequalification of Ethionamide 250 mg Tablets* :

Changes	Product information affected	Accepted on
Addition of manufacturing site for the API		17 February 2010
Change in the shelf life of the FPP	SmPC	11 February 2011
Change in the shelf life of the FPP	SmPC	31 March 2011
Change in the shelf life of the FPP	SmPC, PIL	28 June 2012
Deletion of manufacturing site for the API		22 February 2013
Change in the batch size of the FPP		22 May 2013
Changes to the published information	WHOPAR parts affected	Accepted on
Change in the pack size of the FPP	3, 4, 5	10 August 2015
Addition of a manufacturing and batch control testing site for the FPP	3	11 September 2015

* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.