

Steps taken following Prequalification of Para-aminosalicylate sodium delayed-release granules 60% w/w* :

Changes	Product information affected	Accepted on
Change of immediate packaging material and pack size of the FPP	SmPC, PIL, Labelling	14 September 2010
Change in the in-use shelf-life of the finished product	SmPC, PIL, Labelling	March 22, 2011
Change of batch size of the FPP		04 April 2012
Change in the shelf life of the FPP	SmPC	23 April 2012
Addition of manufacturing and batch release testing site for the FPP	PIL	02 May 2012
Change in the shelf life of the FPP	SmPC	04 June 2012
Change in the batch size of the finished product		11 September 2012
Change of immediate packaging material of the FPP	SmPC, PIL	11 January 2013
Change in the specification of the FPP		03 June 2013
Change in the specification of the FPP		21 July 2013
Changes to the published information	WHOPAR parts affected	Accepted on
Change of immediate packaging material of the FPP	3, 4	09 January 2014

* 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.