

Steps taken following prequalification of [HA392 trade name] *:

Changes	WHOPAR parts affected	Date
Change in the batch size of the FPP		03 December 2008
Addition of manufacturing site for Zidovudine API		28 January 2009
Change in the batch size of the FPP		04 February 2010
Deletion of absorbent cotton filler from HDPE bottle pack	SmPC, PIL	04 March 2010
Change of shelf life of the FPP	SmPC	08 April 2010
Addition of manufacturing site for Lamivudine API		17 May 2010
Change in the shelf life of the FPP	SmPC	27 September 2010
Change in the specification of Zidovudine API		14 January 2011
Change in dimensions of packaging material of the FPP		03 February 2011
Addition of manufacturing block for Zidovudine API		16 February 2011
Change in the name of the supplier and manufacturer of the FPP	SmPC, PIL, labels	18 October 2011
Addition of manufacturing site with change in manufacturing process for Zidovudine API		17 November 2011
Change of shelf life of the FPP	SmPC	27 November 2011
Change in the batch size of the FPP		January 31 2012
Inclusion of alternate screw cap closure for packaging of the FPP		19 April 2012
Addition of manufacturing and batch release testing site for the FPP	PIL	04 June 2012
Addition of manufacturing and batch release testing site for the FPP	PIL	22 October 2012
Change in the batch size of the FPP		29 January 2013
Change in test procedure, alternative packaging configuration and additional manufacturing blocks for Lamivudine API		12 March 2013
Change in the batch size of Zidovudine API		03 April 2013
Addition of manufacturing site for Lamivudine API		13 May 2013
Change in specification and test procedure of Zidovudine API		15 May 2013
Addition of manufacturing site for Zidovudine API		19 June 2013
Change in the batch size of the FPP		31 July 2013
Change in scoring configuration of the tablets involving addition of score line	3, 4	04 November 2015
Change in the name and/or address of the supplier of the FPP	3, 4, 5	01 March 2017
Addition of manufacturing and batch release testing site for the FPP	3	07 April 2017
Change in the container closure system	3, 4	03 May 2017
Requalification	1	24 October 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 2, 3, 4, 5	January, 2024

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Formerly known as "Matrix Lab. Ltd".