

**Steps taken following Prequalification of [HA426 trade name]\***

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Accepted on</b>
Change in the shelf life of the FPP	4	08 April 2010
Change in the shelf-life of the FPP	4	09 May 2011
Deletion of absorbent cotton from the HDPE bottle pack	3, 4, 5	22 June 2011
Change in the name of the supplier and manufacturer of the FPP	3,4,5	18 October 2011
Change in the shelf life of the FPP	4	10 April 2012
Addition of manufacturing and quality control testing site for the FPP	3	20 November 2012
Addition of manufacturing and quality control testing site for the FPP	3	22 January 2013
Addition of manufacturing and quality control testing site for the FPP	3	23 March 2013
Addition of manufacturing and batch control testing site for the FPP	3	26 March 2015
Change in the manufacturing site of the FPP	3	02 July 2016
Addition of FPP manufacturing site	3	09 December 2016
Addition of FPP manufacturing and batch control testing site	3	14 December 2016
Change in the name and/or address of the supplier of the FPP	3, 4, 5	01 March 2017
Product information updated with respect to excipient: lactose	3,4,5	N/A
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3,4,7	December 2019
Addition of FPP primary packaging type	3, 4, 5	01 April 2020
Deletion of FPP manufacturing and testing site	3	12 March 2022

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

<sup>1</sup> Formerly Matrix Laboratories Ltd

