

Steps taken following Prequalification of [HA060 trade name]*

This document will only list changes endorsed by WHO Prequalification Team – Medicines that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Addition of FPP manufacturing site	3	26 February 2006
Change in shelf-life of the FPP involving extension	4	29 May 2008
Change in the package size of the FPP	3, 4, 5	07 April 2010
Addition of a primary packaging type	3, 4, 5	31 August 2010
Addition of FPP manufacturing and testing site	3	28 September 2011
Addition of FPP manufacturing and testing site	3	12 October 2011
Addition of packaging type	3, 4	14 November 2011
Addition of FPP manufacturing and testing site	3	29 November 2011
Addition of FPP manufacturing site	3	03 August 2012
Change in the name and/or address of the FPP manufacturer	3	29 August 2014
Change in shelf-life of the FPP involving extension	4	03 August 2018
Change in product description	3,4	13 March 2019
Requalification	1	18 April 2019
Update of WHOPAR to reflect current WHO guidance and state of scientific knowledge	1,3,4	November 2019
Change of imprints and addition of score line	3, 4	04 January 2021
Change in the name of a manufacturer of the FPP	3	November 2022

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