

**Steps taken following prequalification of [HA286 trade name]\*:**

This document will only list changes endorsed by WHO that affect the WHOPAR.

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Date</b>
Change of immediate packaging material and pack size of the FPP	3,4,5	25 September 2006
Deletion of absorbent cotton from HDPE bottle pack	3,4	17 December 2008
Change of debossing on the tablets to 'GOU' for supplies to Uganda	3,4	03 August 2012
Change in the name and/or address of the FPP supplier and manufacturing site	3,4,5	06 June 2015
Change in the FPP shelf life involving extension; and FPP storage conditions	3,4,5	18 October 2016
Deletion of FPP packaging type	3,4,5	18 October 2016
Requalification	1	30 July 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2,3,4	November 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4,5	November 2023

†Formerly Ranbaxy Laboratories Ltd

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.