

**Steps taken following prequalification of [HA485 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 in the shelf life of the FPP	4	March 2012
Change in the shelf-life of the FPP (HDPE bottle pack of 60s)	4	October 2018
Product information updated with respect to section 4 of the SmPC and PIL	3, 4	November 2018
Requalification	1	1 April 2019
Change in the address of the FPP supplier	3, 4, 5	June 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4, 5	January 2024

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