

Steps taken following prequalification of [MA091 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 pack sizes	3, 4, 5	May 2014
Change in the shelf-life of the FPP involving extension	4	June 2014
Addition of FPP manufacturing and testing site	3	May 2015
Removal of debossing from the tablet	3, 4	August 2015
Addition of FPP manufacturing site	3	October 2015
Change in the shelf life of the FPP involving extension	4	April 2023
General update of the WHOPAR to reflect the current product specifics, WHO guidelines and state of scientific knowledge	3, 4	March 2023
Addition of an FPP packaging type	3, 4, 5	May 2026

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