

Steps taken following prequalification of [MA128 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the package size involving change in the number of units in a package.	3,4,5	December 2018
Change in the shelf-life of the FPP involving extension	4	April 2019
Addition of manufacturing and testing site of the FPP	3	November 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	April 2023
Change in the address of the FPP manufacturer	3	March 2024

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