

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

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

| <b>Changes</b>  | <b>WHOPAR parts affected</b> | <b>Date</b>   |
|---|------------------------------|---------------|
| 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    |
| Change in the corporate office address of the FPP supplier  | 3, 4, 5                      | February 2026 |

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