

Steps taken following prequalification of [TB178 trade name]*:

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

| Changes | WHOPAR parts affected | Date |
|---|------------------------------|---------------|
| Change of immediate packaging material and pack size of the FPP | 3, 4, 5 | December 2008 |
| Change of pack size of the FPP | 3, 4, 5 | May 2010 |
| Addition of a break line to the tablets | 3, 4 | July 2010 |
| Change in the shelf life of the FPP | 4 | December 2010 |
| Change in the shelf life of the FPP | 4 | December 2011 |
| Change of pack size of the FPP | 3, 4, 5 | August 2014 |
| Addition of a manufacturing and batch control testing site for the FPP | 3 | August 2015 |
| Addition of primary packaging type | 3, 4, 5 | June 2019 |
| Requalification | 1 | 18 July 2025 |
| Replacement of an excipient with another comparable excipient | 3, 4 | May 2021 |
| General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge | 3, 4 | March 2023 |
| General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge | 3, 4 | July 2025 |
| Addition of manufacturing site for the FPP | 3 | February 2026 |

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