

### Steps taken following prequalification of [TB285 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>      |
|---|------------------------------|------------------|
| Addition of FPP primary packaging type  | 3, 4, 5                      | July 2020        |
| Change in the address of the FPP manufacturer   | 3                            | August 2024      |
| Requalification   | 1                            | 08 April 2024    |
| General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge | 1, 3, 4                      | June 2025        |
| Change of embossing and addition of score line.   | 2, 3, 4                      | 12 February 2026 |

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