

### Steps taken following prequalification of [TB263 trade name]\*:

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

| Changes  | WHOPAR parts affected | Date          |
|--|-----------------------|---------------|
| Change in the address of the FPP supplier  | 3, 4, 5               | June 2019     |
| Requalification  | 1                     | 24 April 2023 |
| General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge. | 3, 4                  | January 2024  |
| General update of the WHOPAR to reflect the current WHO guidelines and state of scientific knowledge.                                      | 4                     | January 2025  |

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