

Steps taken following Prequalification of [TB391 trade name]*:

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

| Changes | WHOPAR parts affected | Date |
|--|------------------------------|-------------|
| Change in the FPP shelf-life involving extension | 4 | July 2024 |
| Change in the FPP shelf-life involving extension | 4 | July 2025 |

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