

Steps taken following prequalification of [TB397 trade name]*:

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

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

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.