

**Steps taken following prequalification of [TB385 trade name]\*:**

| <b>Changes</b>  | <b>WHOPAR parts affected</b> | <b>Date</b>   |
|---|------------------------------|---------------|
| General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge | 3;4;8                        | November 2025 |

---

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