

Steps taken following Prequalification of [TB383 trade name]*

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

Changes	WHOPAR parts affected	Date
Addition of FPP package size	3, 4, 5	6 July 2022
Addition of FPP manufacturing site	3	18 December 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 3, 4	September 2025

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