

Steps taken following Prequalification of [TB381 trade name]*:

This document will only list changes endorsed by WHO that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Change in the shelf-life of the FPP involving extension	4	25 October 2022
Addition of FPP package size	3, 4, 5	10 May 2023
Change in the FPP shelf-life involving extension	4	5 November 2024
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4	February 2025

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