

Steps taken following Prequalification of [TB193 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 package size of the FPP	3, 4, 5	December 2021
Addition of a manufacturing and batch control testing site of the FPP	3	July 2022
General update of the WHOPAR to reflect the WHO guidelines and state of scientific knowledge	3, 4	December 2022
Change in the FPP shelf-life involving extension	4	February 2023
Change in the FPP shelf-life involving extension	4	November 2023
Change in the FPP shelf-life involving extension	4	December 2024
Addition of FPP manufacturing site	3	February 2025

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