

Steps taken following Prequalification of [TB159 trade name]*

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

Changes	WHOPAR parts affected	Accepted on
Change in the FPP package size	3, 4, 5	December 2021
Change in the FPP package size	3, 4, 5	December 2021
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
Addition of FPP manufacturing site	3	December 2023

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