

Steps taken following Prequalification of [TB173 trade name]*

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

Changes	WHOPAR parts affected	Date
Addition of a primary package type	3,4,5	4 October 2017
Change in the address of the FPP supplier	3,4,5	19 June 2019
Change in the FPP shelf-life involving extension	4	10 October 2019
Requalification	1	06 May 2020
Change in the FPP shelf-life involving extension	4	30 August 2021
Update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1,2, 3, 4	May 2023

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