

Steps taken following prequalification of [TB333 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 involving additional pack size	3,4,5	04 June 2018
Change in the shelf-life of the FPP involving extension	4	24 October 2018
Change in the shelf-life of the FPP involving extension	4	10 January 2020
Change in the shelf-life of the FPP involving extension	4	06 December 2022
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3,4	April 2023

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