

Steps taken following prequalification of [TB237 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	4	February 2014
Addition of embossing on the tablets	3, 4	February 2014
Addition of a primary packaging	3, 4, 5	March 2017
Product information updated with respect to sections 4 of the SmPC and PIL	3, 4	November 2018
Change in the address of the FPP supplier	3, 4, 5	June 2019
Requalification	1	30 September 2019
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4, 5	November 2021
Change in FPP shelf-life involving extension	4	August 2023
General update of the WHOPAR to reflect the current product specifics, WHO guidelines and state of scientific knowledge	3, 4	May 2025

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