

Steps taken following prequalification of [TB068 trade name]*:

This document will only list changes endorsed by WHO that affect the WHOPAR.

Changes	WHOPAR parts affected	Accepted on
Change in the shelf life of the FPP	4	January 2007
Addition of FPP manufacturing and quality control site	3	December 2011
Change in the address of the supplier	3, 4, 5	July 2016
Addition of a primary packing type, additional pack (cold alu/alu blister pack 24x28)	3,4	November 2017
Requalification	1	17 June 2019
Change in the shelf of FPP involving extension from 24 months to 36 months for Alu Alu blister pack	4	March 2021
Addition of primary packaging material	3, 4, 5	July 2023
General update of the WHOPAR to reflect the current WHO guidelines and state of scientific knowledge.	3, 4	July 2025

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