

Steps taken following prequalification of [TB309 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the package size involving additional number of units in a package	3, 4, 5	December 2017
Addition of FPP manufacturing and testing site	3	March 2018
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1, 3, 4, 5	November, 2024
Change in the labelled storage conditions of the FPP	3, 4, 5	February 2025
Addition of FPP manufacturing site	3	February 2026

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