

Steps taken following prequalification of [TB323 trade name]¹:

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

Changes	WHOPAR parts affected	Accepted on
Change in the shelf-life of the FPP involving extension	4	13 April 2019
Change in the address of the FPP supplier	3, 4, 5	19 June 2019
Addition of FPP manufacturing and testing site	3	14 November 2019
Addition of FPP pack size	3, 4, 5	21 October 2020
Change in the shelf-life of the FPP involving extension	4	15 June 2023
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	September 2023

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.