

Steps taken following prequalification of [TB299 trade name]*:

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

Changes	WHOPAR parts affected	Date
Addition of a primary packaging type	3, 4, 5	15 September 2016
Change in the shelf-life of the FPP involving extension	4	27 February 2017
Change in the shelf-life of the FPP involving extension	4	30 November 2020
Update of the WHOPAR to reflect new safety information, the current WHOPAR structure, product specifics, WHO guidelines, and state of scientific knowledge	3, 4	July 2023
Change in the shelf-life of the FPP involving extension	4	13 August 2023

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