

Steps taken following prequalification of [TB297 trade name]*:

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

Changes	WHOPAR parts affected	Date
Change in the FPP shelf-life involving extension	4	18 April 2018
Addition of FPP pack sizes	3, 4, 5	20 November 2018
Change in the FPP shelf-life involving extension	4	06 December 2018
Addition of FPP packaging sizes	3,4,5	10 April 2019
Change in the FPP shelf life involving extension	4	06 April 2020
Update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines, and state of scientific knowledge	2, 3, 4	December 2021
Change in the FPP shelf life involving extension	4	April 2023
Update of the WHOPAR to reflect new safety information, the current WHOPAR structure, product specifics, WHO guidelines, and state of scientific knowledge	3, 4	May 2023
Addition of a packaging site for the FPP	3	May 2025

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