

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 shelf-life of the FPP involving extension	4	18 April 2018
Addition of FPP pack sizes	3, 4, 5	20 November 2018
Change in the shelf-life of the FPP involving extension	4	06 December 2018
Addition of FPP packaging sizes	3,4,5	10 April 2019
Change in the shelf life of the FPP involving extension	4	06 April 2020
General 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 shelf life of the FPP involving extension	4	April 2023

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