

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

Steps taken following Prequalification of [TB381 trade name]*:

Changes	WHOPAR parts affected	Date
Change in the shelf-life of the FPP involving extension	4	25 October 2022
Addition of FPP package size	3, 4, 5	10 May 2023

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