

Steps taken following Prequalification of [TB361 trade name]*

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

Changes	WHOPAR parts affected	Date
Addition of FPP package size (blisters)	3, 4, 5	12 October 2020
Change in the FPP shelf life involving extension	4	06 August 2021
Change in the FPP shelf life involving extension	4	April 2023

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