

Steps taken following Prequalification of [TB350 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	July 2019
General 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
Change in the FPP shelf-life involving extension	4	April 2024

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