

### Steps taken following prequalification of [TB226 trade name] \*:

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

Changes	WHOPAR parts affected	Date
Change in the FPP shelf-life involving extension	4	December 2013
Addition of FPP packaging size	3, 4, 5	February 2019
Addition of FPP manufacturing and testing site	3	February 2019
Requalification	1	May 2020
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	March 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics and WHO guidelines	1, 2, 3, 4, 5	October 2023
Change in the FPP shelf-life involving extension	4	June 2025

<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.