

### 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 shelf-life of the FPP involving extension	4	11 December 2013
Addition of FPP packaging size	3, 4, 5	26 February 2019
Addition of FPP manufacturing and testing site	3	26 February 2019
Requalification	1	06 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

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