

Steps taken following prequalification of [TB196 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 corporate address of the supplier of the FPP	3, 4, 5	11 July 2016
Change in shelf-life of the FPP involving reduction	4	23 May 2019
Deletion of a pack type	3,4,5	23 May 2019
Requalification	1	17 June 2019
Addition of FPP manufacturing site	3	6 April 2022
Withdrawal of a manufacturing site of FPP	3	September 2022
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge.	2, 3, 4	May 2023
Supplementary bioequivalence data	6a	24 November 2017

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