

Steps taken following prequalification of [TB168 trade name]¹:

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

Changes	WHOPAR parts affected	Date
Change of immediate packaging material and pack size of the FPP	3, 4, 5	25 May 2010
Change of FPP primary packaging type	3, 4, 5	24 February 2015
Change in the shelf-life of the FPP	4	24 February 2015
Change of FPP primary packaging type	3, 4	09 June 2015
Addition of a manufacturing site for the FPP	3	21 February 2016
Change in the package size involving change in the number of units in a package	3, 4, 5	02 March 2018
Change in the composition of an immediate-release solid oral dosage form	3, 4	19 April 2018
Change in shelf-life of the FPP (blister packs and strip pack)	4	13 September 2018
Change in the package size involving change in the number of units in a package	3, 4, 5	16 September 2021
Change in the package size involving change in the number of units in a package	3, 4, 5	12 October 2022
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4, 5	March 2023

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