

**Steps taken following Prequalification of [TB183 trade name]\***

Changes	WHOPAR parts affected	Accepted on
Change of immediate packaging material and pack size of the FPP	3, 4, 5	31 May 2010
Change of FPP primary packaging type	3, 4	19 June 2015
Addition of a manufacturing site for the FPP	3	10 February 2016
Additional primary packaging type	3, 4, 5	19 April 2018
Replacement of in-house coating by ready mixture	3, 4	19 April 2019
Change in shelf-life of the FPP involving extension, with change in storage statement	4	10 October 2018
Change in the pack size of the FPP	3, 4, 5	21 August 2022
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	1,2,3,4,5,8	January 2023

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