

**Steps taken following Prequalification of [TB008 trade name] <sup>1</sup>:**

<b>Changes</b>	<b>WHOPAR parts affected</b>	<b>Accepted on</b>
Requalification	1	11 December 2018
Change in the immediate packaging material and pack size of FPP	3, 4, 5	20 May 2010
Change in the shelf-life of the FPP involving extension	4	19 December 2018
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	January 2021
Change in the product appearance	3, 4	19 November 2024

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