

Steps taken following prequalification of [TB172 trade name]*

Changes	Product information affected	Accepted on
Change of immediate packaging material of the FPP	3, 4, 5	09 May 2012
Change in dimensions of the container closure system		05 June 2012
Change of pack size of the FPP	3, 4, 5	19 May 2016
Change of pack size of the FPP	3, 4, 5	20 January 2017
Product information updated with respect to section 4 of the SmPC and PIL	3, 4	November 2018
Change in the address of the FPP supplier	3, 4, 5	19 June 2019

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