

Steps taken following Prequalification of [HA631 trade name]*:

Changes	WHOPAR parts affected	Date
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
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	April 2020
Requalification	1	15 August 2023
Update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	3, 4	September 2024

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