

Steps taken following Prequalification of [HA631 trade name]:

Changes	WHOPAR parts affected	Accepted on
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

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