

Steps taken following Prequalification of [HA553 trade name]¹:

Changes	WHOPAR parts affected	Accepted on
Change in the name of supplier and manufacturer of the FPP	3, 4, 5	02 March 2016
Change in the name of supplier and manufacturer of the FPP	3, 4, 5	03 August 2018
Change in the labelled storage conditions of the FPP	3, 4, 5	09 March 2021
Additional pack sizes of the FPP	3, 4, 5	11 August 2022
Requalification	1	03 August 2021
General update of the WHOPAR to reflect the current WHOPAR structure, product specifics, WHO guidelines and state of scientific knowledge	2, 3, 4	March 2023

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.