

Steps taken following prequalification of [HA635 trade name] *

Changes	WHOPAR parts affected	Date
Change in the pack size of the FPP	3, 4, 5	24 June 2016
Addition of a primary packaging type for the FPP	3, 4	04 July 2016
Addition of manufacturing and testing site for the FPP	3	21 May 2018
Change in appearance of the FPP	3, 4	31 October 2019
Requalification	1	10 May 2022
Change in the product information to reflect current WHO guidelines and state of scientific knowledge	3, 4	July 2026

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.