

Steps taken following prequalification of [HA538 trade name]*:

This document will only list changes endorsed by WHO that affect the WHOPAR.

Changes	WHOPAR parts affected	Date
Change in the pack size of the FPP	3, 4, 5	August 2016
Reduction of the shelf life of the FPP from 36 months to 24 months	4	December 2017
Requalification	1	03 August 2021
General update of the WHOPAR to reflect the current product specifics, WHOPAR structure, WHO guidelines and state of scientific knowledge	3, 4	January 2023
General update of the WHOPAR to reflect the current product specifics, WHO guidelines and state of scientific knowledge	3, 4, 5	May 2026

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