WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA596 trade name]*

Ondansetron (as hydrochloride dihydrate) 8 mg tablets

[HA596 trade name], manufactured at Cadila Pharmaceuticals Limited, Dholka Gujarat, India, was included in the WHO list of prequalified medicinal products for the treatment of conditions associated with HIV/AIDS on 27 August 2015.

[HA596 trade name] is indicated for managing nausea and vomiting induced by cytotoxic chemotherapy, radiotherapy and preventing postoperative nausea and vomiting in HIV patients. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient of [HA596 trade name] is ondansetron hydrochloride dihydrate.

The efficacy and safety of ondansetron are well established based on extensive clinical experience in the management of nausea and vomiting induced by cytotoxic chemotherapy, radiotherapy and preventing postoperative nausea and vomiting.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of ondansetron, the team of assessors advised that [HA596 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA596 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA596 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 August 2015	listed
Pharmaceutical quality	21 January 2015	MR
Bioequivalence	04 February 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	19 August 2015	MR
FPP	13 June 2014	MR
GCP/GLP (re-)inspection	19 December 2013	MR

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
NA: not applicable, not available
PQ: prequalification

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

Requalification	04 November 2021