WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH039 trade name]*

Misoprostol 200 µg tablets

[RH039 trade name], manufactured at Cipla Limited, Goa, India was included in the WHO list of prequalified medicinal products for the treatment of reproductive health conditions in women on 08 April 2014.

[RH039 trade name] is indicated for indicated for induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination with mifepristone). 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 [RH039 trade name] is misoprostol.

The efficacy and safety of misoprostol is well established based on extensive clinical experience in the treatment of induction of labour, prevention of postpartum haemorrhage, induction of abortion (alone in combination with mifepristone or letrozole) and management of incomplete abortion or missed abortion & intrauterine fetal death (alone or in combination with mifepristone).

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 [RH039 trade name] in reproductive health conditions, the team of assessors advised that [RH039 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH039 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH039 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	08 April 2014	listed
Quality	25 March 2014	MR
Bioequivalence	28 March 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	13 April 2013	MR
FPP	30 Nov 2013	MR
GCP/GLP (re-)inspection	01 Feb 2014	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

The table represents the status of relevant completed activities only.

Requalification	04 September 2020

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