

**WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

[RH094 trade name]*

Misoprostol 200µg tablets

[RH094 trade name], manufactured at Mylan Laboratories Limited, Hyderabad, Telangana, India, was included in the WHO list of prequalified medicinal products for the treatment of reproductive health conditions on 02 September 2022.

[RH094 trade name] is 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 [RH094 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 [RH094 trade name] in reproductive health conditions, the team of assessors advised that [RH094 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH094 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH094 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	02 September 2022	listed
Quality	20 August 2022	MR
Bioequivalence	30 August 2022	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	MR
FPP	06 August 2021	MR
GCP/GLP (re-)inspection	NA	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.

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