WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH040 trade name]*

Levonorgestrel 0.75 mg tablets

[RH040 trade name], manufactured at Cipla Limited, Mumbai, India, was jointly accepted by WHO/EAC (East African Community) and included in the WHO list of prequalified products, for the purpose of facilitating the national registration of the product by the countries of EAC, for emergency contraception for women on 8 April 2014..

[RH040 trade name] is indicated for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. 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 (API) of [RH040 trade name] is the second-generation progestin (synthetic progestogen), levonorgestrel.

The efficacy and safety of levonorgestrel are well established based on extensive clinical experience in emergency contraception.

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 levonorgestrel for emergency contraception for women, the team of assessors advised that [RH040 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH040 trade name] in the list of prequalified medicinal products for the purpose of facilitating national registration of the product in the member states of the EAC.

Summary of prequalification status for [RH040 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	8 April 2014	listed
Quality	26 March 2014	MR
Bioequivalence	28 March 2014	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	18 May 2012	MR
FPP	30 Nov 2013	MR
GCP/GLP (re-)inspection	NA	NA
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 MR*: desk review (based on recent inspection reports) 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.

Requalification	3 Jun 2020