WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH065 trade name]*

Levonorgestrel 1.5mg tablets

[RH065 trade name], manufactured at HLL Lifecare Limited, Karnataka, India, was included in the WHO list of prequalified medicinal products for emergency contraception for women on 23 April 2018.

[RH065 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 of [RH065 trade name] is the second-generation progestin (synthetic progestogen), levonorgestrel

The efficacy and safety of levonorgestrel [API] is 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, the team of assessors advised that [RH065 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH065 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH065 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	23 April 2018	listed
Quality	09 April 2018	MR
Bioequivalence	13 April 2018	MR
GMP (re-)inspection		
API	22 December 2017	MR
FPP	19 January 2017	MR
GCP/GLP (re-)inspection	29 September 2017	MR

MR: meets requirements
NA: not applicable, not available

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.