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

## [RH046 trade name]*

Levonorgestrel 1.5 mg tablets

[RH046 trade name], manufactured at Cipla Limited, Verna Goa, India, was included in the WHO list of prequalified medicinal products for emergency contraception for women on 9 July 2015.

[RH046 trade name] is currently indicated for emergency contraceptive to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure. 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 [RH046 trade name] is levonorgestrel.

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

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, the team of assessors advised that [RH046 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH046 trade name] in the list of prequalified medicinal products.

**Summary of prequalification status for [RH046 trade name]:**

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

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

| Initial acceptance | Date | Outcome |
|---|---|---|
| **Status on PQ list** | 09 July 2015 | listed |
| Pharmaceutical quality | 02 July 2015 | MR |
| Bioequivalence | 06 July 2015 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 18 May 2012 | MR |
| FPP | 20 November 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

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|---|---|
| **Requalification** | 20 September 2021 |