WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH068 trade name]*

Levonorgestrel 0,75mg tablets

[RH068 trade name], manufactured at Laboratorios Leon Farma SA, Villaquilambre, Leon 24008, Spain, was included in the WHO list of prequalified medicinal products for emergency contraception for women on 05 February 2021.

[RH068 trade name] is indicated for 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(s) of [RH068 trade name] is levonorgestrel.The efficacy and safety of levonorgestrel is well established based on extensive clinical experience in the treatment of 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 in reproductive health, the team of assessors advised that [RH068 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH068 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH068 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	05 February 2021	listed
Quality	08 December 2020	MR
Bioequivalence	10 December 2020	MR
Safety, efficacy		NA
GMP (re-)inspection		
API	NA	NA
FPP	NA	NA
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
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.