WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH071 trade name]*

Ethinylestradiol/levonorgestrel 0.03 mg/0.15 mg tablets + placebo 0 mg tablets

[RH071 trade name], manufactured at Laboratorios Leon Farma SA, Villaquilambre, Leon 24008, Spain, was included in the WHO list of prequalified medicinal products for female contraception on 21 April 2020.

[RH071 trade name] is indicated as an oral combined hormonal contraceptive (CHC) agent for women. 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 ingredients of [RH071 trade name] are ethinylestradiol and levonorgestrel, two types of female sex hormones, oestrogen and progestogen.

The efficacy and safety of ethinylestradiol and levonorgestrel are well established based on extensive clinical experience in female 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 [RH071 trade name] for contraception, the team of assessors advised that [RH071 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH071 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH071 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 April 2020	listed
Quality	13 Feb 2020	MR
Bioequivalence	18 Feb 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	NA	NA
GCP/GLP (re-)inspection	29 March 2020	MR*

MR: meets requirements
MR*: desk review (based on recent inspection reports)
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.