WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH066 trade name]*

Desogestrel/ethinylestradiol 0.15mg/0.03mg + placebo 0mg tablets

[RH066 trade name], manufactured at Laboratorios Leon Farma SA, Villaquilambre, Leon 24008, Spain, was included in the WHO list of prequalified medicinal products for contraception for women on 27 October 2020.

[RH066 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 [RH066 trade name] are ethinylestradiol and desogestrel, two types of female sex hormones, oestrogen and progestogen.

The efficacy and safety of desogestrel and ethinylestradiol 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 desogestrel and ethinylestradiol for contraception, the team of assessors advised that [RH066 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH066 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH066 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	27 October 2020	listed
Quality	21 October 2020	MR
Bioequivalence	22 October 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	NA	NA
FPP	08 March 2018	MR*
GCP/GLP (re-)inspection	08 August 2019	MR*

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.