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

## [RH066 trade name]*

Desogestrel/ethinylestradiol 150 micrograms/30 micrograms + placebo tablets

[RH066 trade name], manufactured at Laboratorios Leon Farma SA, Villaquilambre, Leon 24193, 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) medicine 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]:**

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** | 27 October 2020 | listed |
| Pharmaceutical quality | 21 October 2020 | MR |
| Bioequivalence | 22 October 2020 | MR |
| Safety, efficacy | NA | NA |
| **GMP (re-)inspection** | | |
| API | 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