

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH108 trade name]*

Ethinylestradiol/levonorgestrel+ Ferrous (fumarate) 0.03mg/0.15mg+75 mg coated tablets

[RH108 trade name], manufactured at Renata PLC, Rajendrapur Potent Product Facility, Noyapara, Bhawal Mirzapur, Rajendrapur, Gazipur 1700, Bangladesh, was included in the WHO list of prequalified medicinal products for contraception for women on 23 March 2026.

[RH108 trade name] is indicated for contraception 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 [RH108 trade name] are ethinylestradiol and levonorgestrel.

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 ethinylestradiol and levonorgestrel in contraception for women, the team of assessors advised that [RH108 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH108 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH108 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	23 March 2026	listed
Pharmaceutical quality	16 March 2026	MR
Bioequivalence	16 March 2026	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	04 July 2024	MR
FPP	18 July 2024	MR
GCP/GLP (re-)inspection	05 June 2023	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 NA: not applicable, not available PQ: prequalification	