WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH013 trade name] *

International Nonproprietary Name(s) (INN)/strength/pharmaceutical form:
Ethinylestradiol/levonorgestrel 30µg/150µg coated tablets

Abstract

[RH013 trade name], manufactured at Mylan Laboratories Ltd, Sarigam, Gujarat, India was included in the WHO list of prequalified medicinal products for contraception for women on 29 September 2011.

[RH013 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 (APIs) of [RH013 trade name] are the synthetic hormones ethinylestradiol and levonorgestrel.

The efficacy and safety profile of [RH013 trade name] is 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 [RH013 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH013 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Summary of Prequalification Status for [RH013 trade name]

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list, i.e. date of listing	29 Sept 2011	listed
Quality	21 July 2010	MR
Bioequivalence	13 Aug 2010	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	NA	NA
FPP	09 Sept 2011	MR
GCP (re-)inspection	NA	NA
Batch Analysis	NA	NA

MR: meets requirements
NA: not applicable, not available

Requalification	31 October 2019	MR

MR: meets requirements