WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

FAMY-POP 30 µg Tablets*
International Nonproprietary Name (INN): levonorgestrel

Abstract

FAMY-POP, manufactured at Jai Pharma Limited, Ahmedabad, Gujarat, India was included on the WHO list of prequalified medicinal products for use as a contraceptive for women on 15 August 2016.

FAMY-POP is a so called progestogen only contraceptive pill containing the synthetic hormone levonorgestrel. It is indicated for oral 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 ingredient (API) of FAMY-POP is levonorgestrel. Levonorgestrel mainly acts by thickening cervical mucus, which prevents sperm penetration. Ovulation is inhibited in few women. Levonorgestrel impairs the gonadotropin peak in the middle of the cycle and the *corpus luteum* function, which can also contribute to the contraceptive effect.

The most frequent adverse events of levonorgestrel include bleeding disturbances such as spotting, intermenstrual bleeding and amenorrhea.

The efficacy and safety profile of levonorgestrel is well established based on extensive clinical experience in female contraception.

On the basis of data submitted and public information on the use of levonorgestrel in contraception for women, the team of assessors advised that FAMY-POP is of acceptable quality, efficacy and safety to allow inclusion of FAMY-POP in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

Summary of Prequalification Status for FAMY-POP:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	15 Aug 2016	listed				
Dossier Evaluation (Quality assurance)						
Quality	15 July 2016	MR				
Bioequivalence	08 Aug 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	21 April 2016	MR				
GCP/GLP (re-)inspection	18 Oct 2012	MR				

MR: meets requirements
NA: not applicable, not available