WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Zinnia P *

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

Abstract

Zinnia P, manufactured at Famy Care Ltd, Sarigam, Gujarat, India was included in the WHO list of prequalified medicinal products for contraception for women on 21 October 2013.

Zinnia P 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 Zinnia P are the synthetic hormones ethinylestradiol and levonorgestrel.

The most frequent adverse events observed during use of ethinylestradiol and levonorgestrel were headache (including migraine), spotting and intermenstrual bleeding.

The use of combined oral contraceptives is associated with an increased risk of various serious diseases, such as cardiac infarction, thromboembolism, stroke and hepatic neoplasia. The presence of other risk factors, such as increased blood pressure, hyperlipidaemia, overweight and diabetes additionally increases the morbidity and mortality risk. Smoking increases the risk of these serious undesirable cardiovascular effects. This risk increases with age and cigarette consumption. Therefore, women over 30 should not smoke, if they are using hormonal contraceptives.

Other serious safety concerns with ethinylestradiol and levonorgestrel are angio-oedema, severe allergic (anaphylactic) reactions, high blood pressure and gallbladder disease including gallstones.

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

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 Zinnia P is of acceptable quality, efficacy and safety to allow inclusion of Zinnia P in the list of prequalified medicinal products.

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

Summary of Prequalification Status for Zinnia P

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	21 Oct 2013	listed				
Dossier Evaluation (Quality assurance)						
Quality	19 Sept 2013	MR				
Bioequivalence	03 Oct 2013	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	09 Sept 2011	MR				
GCP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available