WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Levonorgestrel and Ethinyl Estradiol Tablets USP [1]

Levonorgestrel/Ethinylestradiol 150µg/30µg Tablets
+ Placebo tablets – 91-day cycle per pack (84 active and 7 inert tablets)

Levonorgestrel and Ethinyl Estradiol Tablets USP was submitted in 2013 by Lupin Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for female contraception on 26 August 2013.
Information on the site(s) involved in the manufacture of the product and the APIs is available at the products listing information(https://extranet.who.int/pqweb/medicine/4008)

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the "U.S. Food and Drug Administration" (http://www.fda.gov/), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].
Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 30°C. Avoid excursions above 30°C.
- The shelf-life at this storage condition is 24 months.

[1] 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.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.
For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA: (Drugs@FDA: FDA-Approved Drugs
(New Drug Application (NDA): 091440)

The English language version of the Prescribing Information and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.
This WHOPAR for Levonorgestrel and Ethinyl Estradiol Tablets USP is comprised of parts 2, 3. 4. 5 and 7.

Levonorgestrel and Ethinyl Estradiol Tablets USP contains the synthetic hormones levonorgestrel and ethinylestradiol.
Its WHO recommended use is for contraception for women.

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

Summary of Prequalification Status for Levonorgestrel and Ethinyl Estradiol Tablets USP

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	26 August 2013	listed	08 March 2023	listed
Dossier Evaluation	August 2013	MR	February 2023	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.