WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Microlut 30 µg überzogene Tabletten [1]

Levonorgestrel 30µg Tablets

Microlut 30 microgrammes, coated tablets was submitted in 2007 by Bayer Schering Pharma AG to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for female contraception on 26 May 2009.
Information on the site(s) involved in the manufacture of the product and the API is available at the at the products listing information https://extranet.who.int/pqweb/medicine/3990
After prequalification the marketing authorization holder changed to Jenapharm GmbH & Co. KG.

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 German "Federal Institute for Drugs and Medicinal Devices" BfArM, (https://www.bfarm.de/EN/Home/home_node.html) 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. Store in the original package in order to protect from moisture.
- The shelf-life at this storage condition is 60 months.

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (https://www.bfarm.de/EN/Home/home_node.html) resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

[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

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.
The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "BfArM" approved texts, are included in this WHOPAR.
The most recent German product information can be found at:
(http://www.pharmnet-bund.de/dynamic/en/am-info-system/index.html)
MA No. 6929492.00.00)

This WHOPAR for Microlut is comprised of parts 2, 3. 4. 5 and 7.

Microlut is a so-called progestogen only contraceptive pill containing the synthetic hormone levonorgestrel. Its WHO recommended use is for oral contraception for women.

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

Summary of Prequalification Status for Microlut 30 microgrammes, coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	26 May 2009	listed	28 Sept 2017	listed
Dossier Evaluation	12 May 2009	MR	17 Dec 2016	requalified

MR: meets requirements

The table represents the status of relevant completed activities only.