

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Microlut 30 µg coated tablets ¹

Levonorgestrel 30 µg sugar coated tablets

Microlut 30 µg 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 products listing information: <https://extranet.who.int/prequal/medicines/rh002>

The “Procedure for prequalification of pharmaceutical products²” 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 Medical Devices “BfArM”, (https://www.bfarm.de/EN/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 Applicant⁴.

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:

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=8aac767d_2

⁴ https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- 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 resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval. (<https://portal.dimdi.de/amguifree/am/search.xhtml> Reg No 6929492.00.00)

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, as certified to be "BfArM" approved texts and the labelling, are included in this WHOPAR.

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

Microlut contains levonorgestrel. Its WHO recommended use is for oral contraception for women.

Summary of Prequalification Status for Microlut 30 µg coated tablets

	Initial Acceptance		Requalification		Requalification	
	Date	Outcome	Date	Outcome	Date	Outcome
Status on PQ list	26 May 2009	listed	28 Sept 2017	listed	29 Sept 2025	listed
Dossier Evaluation	May 2009	MR	Dec 2016	requalified	Sept 2025	requalified
PQ: prequalification MR: meets requirements						

The table represents the status of relevant completed activities only.