WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Microgynon 28 150 micrograms / 30 micrograms coated tablets[1]

Ethinylestradiol/Levonorgestrel, 30µg/150µg sugar coated tablets + sugar coated placebo tablets

Microgynon 28 150 micrograms / 30 micrograms coated tablets was submitted in 2017 by Jenapharm GmbH & Co. KG to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for reproductive health conditions in women on 24 October 2017.

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/prequal/medicines/rh082

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 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 Applicant[4].

[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/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

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. Protect from moisture.
- The shelf-life at this storage condition:
  - 36 months when packaged in PVC/PE.EVOH.PE/PCTFE-Alu blister cards
  - 24 months when packaged in PVC-Alu blister cards

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (https://www.bfarm.de/EN/Home/_node.html) 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 Zul.-Nr./Reg.-Nr. 6929523.00.00)

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, are included in this WHOPAR.

This WHOPAR for Microgynon 28 is comprised of parts 2, 3. 4. 5 and 7.

Microgynon 28 contains the synthetic hormones ethinylestradiol and levonorgestrel.
Its WHO recommended use is for contraception for women.

Summary of Prequalification Status for
Microgynon 28 150 micrograms / 30 micrograms coated tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	24 October 2017	listed	14 January 2025	listed
Dossier Evaluation	October 2017	MR	January 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.