WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Mirena 20 micrograms/24 hours intrauterine delivery system [1]

Levonorgestrel 20 micrograms/24 hours intrauterine delivery system

Mirena 20 micrograms/24 hours intrauterine delivery system was submitted in 2021 by Bayer AG, Germany. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for reproductive health conditions in women on 17 March 2022.

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/rh100

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 Finnish Medicines Agency "Fimea" (https://www.fimea.fi/etusivu) 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.
- The shelf-life at this storage condition is 36 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://fimea.fi/en/databases_and_registers/fimeaweb?query=Mirena&humanmed=true&selfcare=true&receptmed=true&marketedmed=true&prefillonly=false MA-number 10212

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 "Fimea" approved texts, are included in this WHOPAR.
This WHOPAR for Mirena is comprised of parts 2, 3. 4. 5 and 7.

Mirena contains levonorgestrel. Its WHO recommended use is for female contraception.

Summary of Prequalification Status for
Mirena 20 micrograms/24 hours intrauterine delivery system:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 March 2022	listed
Quality	March 2022	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.