

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Cerazette 75 microgram film-coated tablets¹

Desogestrel 75 µg film-coated tablets

Cerazette 75 microgram film-coated tablets was submitted in 2022 by N.V. Organon. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for contraception for women on 05 May 2023.

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/pqweb/medicine/4456>)

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 Swedish Medical Products Agency “lakemedelsverket” (<https://www.lakemedelsverket.se/en>), 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=8aae767d_2

⁴ [https://extranet.who.int/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf](https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf)

- Do not store above 30°C.
- Store the blister pack in the original sachet in order to protect from light and moisture.
- The shelf-life at this storage condition is 36 months.
- In-use period: Use within one month after first opening of the sachet.

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://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel?id=19971212000066>

(No 13484)

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 as approved by Swedish Medical Products Agency (which uses this structure of product information and publishes it in English on its website).

This WHOPAR for Cerazette is comprised of parts 2, 5 and 7.

Cerazette contains the synthetic hormone desogestrel. Its WHO recommended use is for is for contraception for women.

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

Summary of Prequalification Status for Cerazette 75 microgram film-coated tablets

Initial acceptance	Date	Outcome
Status on PQ list	05 May 2023	listed
Quality	May 2023	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.