WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Tomonil 1.5 mg Tablet[1]

Levonorgestrel 1.5 mg Tablet

Tomonil 1.5 mg tablet was submitted in 2020 by Naari BV. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for emergency contraception for women on 01 July 2021.

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/rh098

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 Swedish Medical Product Agency "Läkemedelsverket" (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 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 the tablet in the blister in the provided carton.
- The shelf-life at this storage condition is 48 months.

[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

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=20170721000017)
MT-nummer: 56750)

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "Läkemedelsverket" approved texts, are included in this WHOPAR.

This WHOPAR for Tomonil 1.5 mg tablet is comprised of parts 2, 3. 4. 5 and 7.

Tomonil 1.5 mg tablet contains levonorgestrel. Its WHO recommended use is for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

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

Summary of Prequalification Status for Tomonil 1.5 mg tablet

Initial acceptance	**Date**	**Outcome**
Status on PQ list	01 July 2021	listed
Quality	June 2021	MR

MR: meets requirements

The table represents the status of relevant completed activities only.