WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Desolett 28 tablets [1]

Desogestrel/Ethinylestradiol 150 micrograms /30 micrograms tablets

Desolett 28 tablets was submitted in 2010 by N.V. Organon. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for contraception for women on 29 September 2010.

Information on the sites involved in the manufacture of the product and the APIs is available at the products listing information: https://extranet.who.int/prequal/medicines/rh025

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 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 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.
- The shelf-life at this storage condition is 36 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=19920124000046 (MT11489)

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 "Läkemedelsverket" approved texts, are included in this WHOPAR.

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

Desolett 28 contains desogestrel and ethinylestradiol. Its WHO recommended use is for female contraception.

Summary of Prequalification Status for Desolett 28 tablets

	Initial Acceptance		**Requalification**		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list	29 September 2010	listed	02 February 2018	listed	15 July 2025	listed
Dossier Evaluation	September 2010	MR	February 2018	requalified	July 2025	requalified

PQ: prequalification
MR: meets requirements

The table represents the status of relevant completed activities only.