WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Misofar 25 micrograms vaginal tablets[1]

Misoprostol 25 micrograms vaginal tablets

Misofar 25 micrograms vaginal tablets was submitted in 2021 by BIAL-Portela & C[a], S.A. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of reproductive health conditions in women on 16 December 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/rh099)

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 (PQT/MED), is based on the approval by the Spanish regulatory authority "Agencia Española de Medicamentos y Productos Sanitarios" (AEMPS, https://www.aemps.gob.es/), 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 PQT/MED 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 25°C. Avoid excursions above 30°C.
- The shelf-life at this storage condition is 36 months.

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[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://cima.aemps.es/cima/publico/detalle.html?nregistro=69682
Marketing authorisation number: 69682)

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 "AEMPS" approved texts, are included in this WHOPAR.
This WHOPAR for Misofar 25 micrograms vaginal tablets is comprised of parts 2, 3. 4. 5 and 7.

Misofar 25 micrograms vaginal tablets contains the synthetic prostaglandin analogue misoprostol. WHO-recommended uses for vaginally administered misoprostol are the induction of labour as well as spontaneous and induced abortion.

It should be prescribed and administered in accordance with countries' national laws and regulations. The most recent official guidelines should be taken into consideration for deciding on the appropriateness of therapy with vaginally administered misoprostol.

Summary of Prequalification Status for: Misofar 25 micrograms vaginal tablets

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	16 December 2021	listed	12 August 2026	listed
Dossier Evaluation	November 2021	MR	August 2026	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.