WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Fall Back Solo™ [1]

Levonorgestrel 1.5 mg uncoated tablet

Fall Back Solo™ was submitted in 2015 by Lupin Limited. to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for emergency contraception for women on 16 December 2015.

Information on the site involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/prequal/medicines/rh058

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 United States "Food and Drug Administration" (https://www.fda.gov), 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 25°C. Store in the original package to protect from light.
- 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

For details on the uses of this product, for relevant efficacy and safety information, see the Prescribing Information as approved by USFDA
https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process
(New Drug Application (ANDA): 201446)

The English language version of the Patient Information and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.
Since a separate information for the health care provider is not available, part 4 is not included in this WHOPAR.

This WHOPAR for Fall Back Solo™ is comprised of parts 2, 3, 5 and 7.

Fall Back Solo™ contains levonorgestrel. Its WHO recommended use is for emergency contraception for women.

Summary of Prequalification Status for Fall Back Solo™

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	16 December 2015	listed	28 July 2025	listed
Dossier Evaluation	October 2015	MR	July 2025	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.