# WHO Prequalification Programme
# WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

**Fall Back Solo®**[1]

International Nonproprietary Name (INN):
Levonorgestrel 1.5mg Tablet

## Abstract

Fall Back Solo®, manufactured at Lupin Limited was submitted to be considered for prequalification in 2015 when the product was licensed / registered in at least one of the ICH regions and subsequently accepted for the WHO list of prequalified products for emergency contraception for women on 16 Dec 2015.

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 of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the U.S. Food and Drug Administration (http://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, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III and IVa climatic conditions, based on available stability information:
Do not store above $25^0$C. Store in the original package.

Based on the above, this WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification (www.fda.gov/drugsatfda FDA Application No. 091328, last accessed March 2016).
The English language version of the Patient Information Leaflet and the labelling, as certified to be FDA approved texts, are included in this WHOPAR.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.
[2] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf

Parts 2a, 2b, 3, 5 and 7 of the WHOPAR for Fall Back Solo® are included here.
Since a separate information for the health care provider is not available, part 4 is not included in this WHOPAR.

Fall Back Solo®, contains levonorgestrel. Its recommended use is for emergency contraception.
The most frequent adverse events observed during treatment with levonorgestrel were nausea, abdominal pain, fatigue, headache, dizziness, breast tenderness and menstrual changes.

The efficacy and safety profile of levornogestrel is well established based on the extensive clinical experience.

**Summary of Prequalification Status for Fall Back Solo®**

| | **Initial Acceptance** | | | |
|---|---|---|---|---|
| | **Date** | **Outcome** | **Date** | **Outcome** |
| Status on PQ list, i.e. date of listing | 16 Dec 2015 | listed | | |
| Dossier Evaluation | 02 Oct 2015 | MR | | |

MR: meets requirements

The table represents the status of relevant completed activities only.