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

**Mifegyne 200 mg tablets**[1]
International Nonproprietary Name (INN):
Mifepristone

## Abstract

Mifegyne 200 mg tablets, manufactured at EXELGYN 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 medical termination of a developing intra-uterine pregnancy on 23 May 2016.

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 Dutch Medicines Evaluation Board "CBG-MEB" (http://english.cbg-meb.nl/), 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, IVa and IVb climatic conditions, based on available stability information:
"Do not store above $25^0$C.
Store in the original package. The shelf life at this storage condition is 48 months."

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 (http://english.cbg-meb.nl/medicines-information-bank Application No. RVG 24206, last accessed July 2016).
The English language version of the Patient Information Leaflet, the Summary of Product Characteristics and the labelling, as certified to be Dutch authorities approved texts, are included in this WHOPAR.

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Mifegyne 200 mg tablets are included here.

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[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

Mifegyne 200 mg tablets tablets contains mifepristone.

The most frequent adverse events observed during treatment with mifepristone were headache, nausea, vomiting, diarrhoea, gastric discomfort and abdominal pain, uterine spasm, fatigue, fever and dizziness.

The most serious adverse effects of mifepristone are heavy uterine bleeding, haemorrhagic shock, uterine rupture, myocardial infarction, gastric bleeding, hepatic and renal failure and anaphylaxis.

The efficacy and safety profile of mifepristone is well established, based on the extensive clinical experience in the management of the medical termination of a developing intra-uterine pregnancy.

**Summary of Prequalification Status for Mifegyne 200 mg tablets**

| | **Initial Acceptance** | | | |
|---|---|---|---|---|
| | **Date** | **Outcome** | **Date** | **Outcome** |
| Status on PQ list, i.e. date of listing | 23 May 2016 | listed | | |
| Dossier Evaluation | 18 April 2016 | MR | | |

MR: meets requirements

The table represents the status of relevant completed activities only.