WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Mifepristone 200 mg Tablets[1]

International Nonproprietary Name (INN)
Mifepristone

Abstract

Mifepristone 200mg Tablets , manufactured at China Resources Zizhu Pharmaceutical Co. Ltd, No. 27, Chaoyang North Road, Chaoyang District, Beijing 100024, P.R. China was included in the WHO list of prequalified medicinal products for reproductive health in women on 15 August 2016.

Mifepristone 200mg Tablets is indicated for medical termination of developing intra-uterine pregnancy, softening and dilatation of the cervix uteri prior to surgical termination of pregnancy during the first trimester and preparation for the action of prostaglandin analogues in the termination of pregnancy for medical reasons.

Mifepristone 200mg Tablets should be prescribed and administered in accordance with countries' national laws and regulations.

Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Mifepristone 200mg Tablets is mifepristone, a progesterone receptor modulator.

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

The most serious adverse events reported are heavy uterine bleeding, haemorrhagic shock, uterine rapture, myocardial infarction, gastric bleeding, hepatic and renal failure and anaphylaxis.

The efficacy and safety profile of Mifepristone 200mg Tablets is well-established, based on extensive clinical experience in women for the indicated conditions.

On the basis of data submitted and public information on the use of mifepristone for reproductive health in women, the team of assessors advised that Mifepristone 200mg Tablets is of acceptable quality, efficacy and safety to allow inclusion of Mifepristone 200mg Tablets in the list of pre qualified medicinal products.

[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.

Summary of Prequalification Status for Mifepristone 200mg Tablets

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	15 Aug 2016	listed				
Dossier Evaluation (Quality assurance)						
Quality	19 May 2016	MR				
Bioequivalence	21 June 2016	MR				
Safety, Efficacy	NA	NA				
Inspection Status						
GMP(re-)inspection						
API	16 Oct 2015	MR				
FPP	28 Jan 2016	MR				
GCP/GLP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available