WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH074 trade name] [1]

Medroxyprogesterone acetate 150mg/mL Suspension for Injection

Abstract

[RH074 trade name], manufactured at Mylan Laboratories Limited, Tal-Sanand, Ahmedabad, India, was included in the WHO list of prequalified medicinal products for contraception in women on 31 October 2018.

[RH074 trade name], is indicated in long term female contraception. 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 [RH074 trade name], is the synthetic hormone medroxyprogesterone acetate. The API is well established and documented for long term female contraception.

The most serious safety concerns with medroxyprogesterone acetate are breast disorders, anaphylactic reactions, depression, thrombosis and abnormal hepatic function.

The most frequent adverse reactions reported are insomnia, irritability, decreased libido, dizziness, headache, acne, menstrual irregularity, dysmenorrhea and injection site reaction.

The efficacy and safety profile of medroxyprogesterone acetate is well established based on extensive clinical experience of contraception in women.

On the basis of data submitted and public information on the use of medroxyprogesterone acetate for contraception in women, the team of assessors advised that [RH074 trade name], is of acceptable quality, efficacy and safety to allow inclusion of [RH074 trade name], in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH074 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	31 October 2018	listed
Quality	17 October 2018	MR
Bioequivalence	22 October 2018	MR
Safety, Efficacy	NA	NA
GMP(re-)inspection		
API	NA	NA
FPP	NA	NA
GCP (re-)inspection	15 December 2017	MR
GLP (re-)inspection	08 September 2018	MR

MR: meets requirements
NA: not applicable, not available

[1] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.