

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH090 trade name]*

Medroxyprogesterone acetate 150mg/mL suspension for injection

[RH090 trade name], manufactured at P.T. Tunggal Idaman Abdi, Jakarta, Timur, Indonesia, was included in the WHO list of prequalified medicinal products for contraception in women on 01 July 2021.

[RH090 trade name] is indicated for long-term contraception in women aged over 18 years. 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 of [RH090 trade name] is the synthetic hormone medroxyprogesterone acetate. The API is well established and documented for long term female contraception.

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

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

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 [RH090 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [RH090 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [RH090 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	01 July 2021	Listed
Quality	03 June 2021	MR
Bioequivalence	14 June 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	05 November 2020	MR*
FPP	21 May 2018	MR
GCP/GLP (re-)inspection	19 March 2021	MR
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

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