

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH074 trade name]*

Medroxyprogesterone acetate 150 mg/mL suspension for injection

[RH074 trade name], manufactured at Senador Laboratories Private Limited, Sanad, Gujarat, India, was included in the WHO list of prequalified medicinal products for contraception in women on 31 October 2018.

[RH074 trade name] is currently indicated for contraception in women. 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 [RH074 trade name] is medroxyprogesterone acetate.

The efficacy and safety of medroxyprogesterone acetate are 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, 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]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

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

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