WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB361 trade name]*

clofazimine 50 mg tablets

[TB361 trade name], manufactured at Oxalis Labs, Lodhimajra, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 16 September 2020.

[TB361 trade name] is indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by *Mycobacterium tuberculosis*. 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 [TB361 trade name] is the antibiotic clofazimine. The efficacy and safety of clofazimine is well established based on extensive clinical experience in the treatment of tuberculosis.

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 clofazimine in the treatment of tuberculosis, the team of assessors advised that [TB361 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB361 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB361 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 September 2020	listed
Quality	10 September 2020	MR
Bioequivalence	14 September 2020	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	27 August 2020	MR*
FPP	16 March 2018	MR
GCP/GLP (re-)inspection	NA	NA

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.