

WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB362 trade name]*

Clofazimine 100 mg tablets

[TB362 trade name], manufactured at Oxalis Labs, Baddi, Himachal Pradesh, India, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 16 September 2020.

[TB362 trade name] is currently 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 [TB362 trade name] is 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, the team of assessors advised that [TB362 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB362 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB362 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 | 16 September 2020 | Listed |
| Pharmaceutical 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 | 14 July 2020 | 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.