WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[TB364 trade name]*

Clofazimine 100 mg soft capsules

[TB364 trade name], manufactured at Suheung Co. Ltd. and Dong-A ST Co. Ltd., Chungcheongnam-do, Republic of Korea, was included in the WHO list of prequalified medicinal products for the treatment of tuberculosis on 26 January 2021.

[TB364 trade name] is indicated for 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 [TB364 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 [TB364 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [TB364 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [TB364 trade name]:

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

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

Initial acceptance	**Date**	**Outcome**
Status on PQ list	26 January 2021	listed
Pharmaceutical quality	02 November 2020	MR
Bioequivalence	03 November 2020	MR
Safety, efficacy		NA
GMP (re-)inspection		
API	08 November 2019	MR
FPP	12 April 2019	MR
FPP	27 August 2020	MR*
GCP/GLP (re-)inspection		
GCP	24 July 2020	MR*
GLP	29 September 2017	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