WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA769 trade name]*

Flucytosine 500 mg tablets

[HA769 trade name], manufactured at Macleods Pharmaceuticals Limited, Pithampur, Dhar, Madhya Pradesh, 454774, India, was included in the WHO list of prequalified medicinal products for the treatment of fungal infections on 25 April 2024.

[HA769 trade name] is indicated together with other systemic antifungals for the treatment of susceptible severe or systemic fungal infections such as candidiasis, cryptococcosis (including cryptococcal meningitis), chromoblastomycosis and certain forms of aspergillosis. 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 [HA769 trade name] is flucytosine.

The efficacy and safety of flucytosine are well established based on extensive clinical experience in the treatment of fungal infections.

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 flucytocine in fungal infections, the team of assessors advised that [HA769 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA769 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA769 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	25 April 2024	listed
Pharmaceutical quality	19 April 2024	MR
Bioequivalence	21 April 2024	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	26 June 2023	MR
FPP	19 November 2021	MR
GCP/GLP (re-)inspection	10 February 2023	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.