

WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

ANCOTIL 500 mg tablet ¹

Flucytosine 500 mg Tablets

ANCOTIL 500 mg tablet was submitted in 2017 by Mylan Laboratories Ltd, India to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the management of HIV/AIDS related conditions on 14 March 2018.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information <https://extranet.who.int/prequal/medicines/ha693>

The “Procedure for prequalification of pharmaceutical products²” defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm), is based on the approval by the French “Agence nationale de sécurité du médicament et des produits de santé” (ANSM, <http://ansm.sante.fr/>), in line with the “Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities”³

National Agency for the Safety of Medicine and Health Products (ANSM)

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.

However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant⁴.

Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

¹ Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority’s responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

² https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

³ https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

⁴ https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- Do not store above 25°C. Store in the original bottle. Keep the bottle tightly closed in order to protect from moisture. Do not remove the desiccant canister.
- The shelf-life at this storage condition is 24 months.

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

<https://base-donnees-publique.medicaments.gouv.fr/extrait.php?specid=68758674>

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.

[Résumé des caractéristiques du produit - ANCOTIL 500 mg, comprimé - Base de données publique des médicaments \(medicaments.gouv.fr\)](#)

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be ANSM approved texts, are included in this WHOPAR.

This WHOPAR for ANCOTIL 500 mg tablet is comprised of parts 2, 3, 4, 5 and 7.

For products for which the WHO recommended uses differ from those authorized by the reference authority, additionally parts 3a, 4a and 5a are included.

ANCOTIL contains flucytosine. Its WHO recommended use is for the treatment of fungal infections in combination with another antifungal agent in HIV/AIDS patients.

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

Summary of Prequalification Status for ANCOTIL 500 mg tablet

Initial acceptance	Date	Outcome
Status on PQ list	14 March 2018	listed
Quality	March 2018	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.