# 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 treatment 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/pqweb/medicine/3628

The "Procedure for prequalification of pharmaceutical products[2]" 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" (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].

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 Applicant[4].

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:

- 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.

[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/pqweb/sites/default/files/documents/48 Stability data SRA FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority's website (http://agence-prd.ansm.sante.fr/php/ecodex/index.php#result) resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval.

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. (agence-prd.ansm.sante.fr/php/ecodex/frames.php?specid=68758674&typedoc=R&ref=R0386068.htm (NUMERO(S) D'AUTORISATION 34009 317 964 3 5)

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "ansm.sante" approved texts, are included in this WHOPAR.
This WHOPAR for ANCOTIL 500 mg tablet is comprised of parts 2, 3. 4. 5 and 7.

ANCOTIL 500 mg tablet 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 |
| Dossier Evaluation | March 2018 | MR |
| PQ: prequalification<br>MR: meets requirements | | |

The table represents the status of relevant completed activities only.