WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Itraconazole 100 mg capsules, hard[1]

International Nonproprietary Name (INN):
Itraconazole 100mg capsules

Itraconazole 100 mg capsules, hard, manufactured at LABORATORIOS LICONSA S.A. Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo, 19200 Azuqueca de Henares (Guadalajara) SPAIN, was submitted to be considered for prequalification in 2018 for the product that is licensed / registered in the United Kingdom and subsequently accepted for the WHO list of prequalified products for the treatment of HIV/AIDS related conditions on 17 July 2018.

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 a stringent regulatory authority (SRA), the United Kingdom Medicines and Healthcare products Regulatory Agency "MHRA" (http://www.gov.uk/mhra), 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. Avoid excursions above 30°C.

The shelf-life at this storage condition is 24 months

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[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.
*Formerly: "UNIVERSAL FARMA, S.L"
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex5.pdf?ua=1
[4] https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

This WHOPAR refers to the information available at the approving (www.gov.uk/mhra) stringent regulatory authority's website 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 and for side effects and warnings, see the Prescribing Information as approved by UK MHRA:
https://products.mhra.gov.uk/search/?search=PL+23218%2F0198&page=1 (PL 23218/0198)

Parts 2, 5 and 7 of the WHOPAR for Itraconazole 100 mg capsules, hard are included here.

Itraconazole 100 mg capsules, hard contains itraconazole. Its WHO recommended use is for the treatment of fungal infections in HIV/AIDS patients.

The efficacy and safety profile of itraconazole. is well established based on the extensive clinical experience in the treatment of HIV/AIDS related infections.

Summary of Prequalification Status for Itraconazole 100 mg capsules, hard

Initial acceptance	**Date**	**Outcome**
Status on PQ list	17 July 2018	listed
Quality	July 2018	MR

MR: meets requirements

The table represents the status of relevant completed activities only.