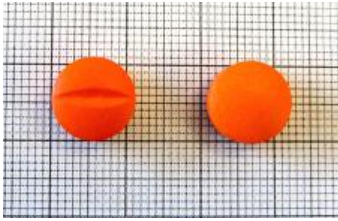


Prequalified Medicinal Products



Reference Number: TB239

Date of prequalification: 25 February 2013

Basis of listing: Prequalified by WHO

Status: Active

INN: Protionamide

Therapeutic area: Tuberculosis

Dosage form & strength: Tablet, Film-coated 250mg

Storage condition: Do not store above 30°C

Shelf life (months): 36

Packaging: Bottle HDPE: 100x1; Blister Alu/PVC/PVdC: 10x10, 14x10

Applicant:

Micro Labs Ltd, 31 Race Course Road, Bangalore, Karnataka, 560 001, India

FPP Manufacturing Site:

Micro Labs Ltd, Unit 3, 92 Sipcot Industrial Complex, Hosur, Tamil Nadu, 635 126, India

FPP WHO Public Inspection Reports:

M **Micro Labs Limited - Unit-3 - (07 - 10 December 2015),**
📍 Hosur, India

API Manufacturing Site:

(Protionamide) Pen Tsao Chemical & Pharmaceutical Industry Co. Ltd, No 2 Tieli Road, Wusong, Shanghai, 200 940, China (People's Republic of)

API WHO Public Inspection Reports:

M **Pen Tsao Chemical & Pharmaceutical Industry Co Ltd - (04 - 07 July 2017),**
📍 Shanghai, China

WHO Public Assessment Reports

[📄 Part 1](#), [📄 Part 2a](#), [📄 Part 2b](#), [📄 Part 3](#), [📄 Part 4](#), [📄 Part 5](#), [📄 Part 6](#), [📄 Part 7](#), [📄 Part 8](#)

Part 1 - Abstract

Part 2 - All accepted presentations (including photo)

Part 3 - WHO-PQ recommended patient information leaflet*

Part 4 - WHO-PQ recommended summary of product characteristics*

Part 5 - Label

Part 6 - Discussion (status at the time of prequalification)

Part 7 - Steps before Prequalification

Part 8 - Steps following Prequalification (from 01 March 2014, only changes to the published information are included)

** This summary of product characteristics/patient information leaflet focus on uses of the medicine covered by WHO Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

<https://www.facebook.com/WHO>