World Health Organization

WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)

Prequalified Medicinal Products

Reference Number: HA526

Date of prequalification: 14 June 2013

Basis of listing: Prequalified by WHO

Status: Active

INN: Zidovudine

Therapeutic area: HIV/AIDS

Dosage form & strength: Solution, Oral 10mg/mL

Storage condition: Do not store above 30°C

Shelf life (months): 18

Packaging: Bottle HDPE: 240mlx1, 100mlx1

Applicant:
Macleods Pharmaceuticals Ltd, 304 Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India

FPP Manufacturing Site:
Macleods Pharmaceuticals Ltd, Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India

API Manufacturing Site:
(Zidovudine) Hetero Labs Limited, Unit 9, Plot 2, Hetero Infrastructure SEZ - Ltd, N Narasapuram Village, Nakkapalli Mandal, Visakhapatnam District, Andhra Pradesh, 531 081, India
(Zidovudine) Shanghai Desano Chemical Pharmaceutical Co Ltd, 417 Binhai Road, Laogang Town, Pudong New Area, Shanghai, 201 302, China (People's Republic of)

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API WHO Public Inspection Reports:

- M **Mylan Laboratories Ltd (Unit-1) - Desk Review** - (07 October 2019),
  Gaddapotharam, India
- M **Mylan Laboratories Limited, Unit-9 - Desk Assessment** - (28 June - 09 July 2021),
  Andhra Pradesh, India
- M **Shanghai Desano Chemical Pharmaceutical Co Ltd** - (15 - 18 January 2019),
  Shanghai, China
- M **Zhejiang Langhua Pharmaceutical Co Ltd - Desk Review** - (10 October 2019),
  Zhejiang Province, China
- M **Mylan Laboratories Ltd (Unit-2) - Desk Review** - (07 October 2019),
  Gaddapotharam, India

WHO Public Assessment Reports

Part 1, Part 2, 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.*

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