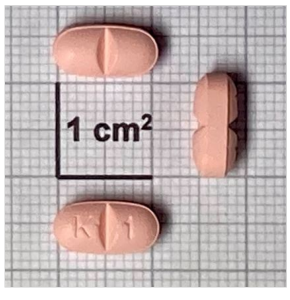
World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

M Medicines

HA765



Digitally signed by Moraru Grigore
Date: 2023.10.09 10:35:58 EEST
Reason: MoldSign Signature
Location: Moldova

Product Details:

WHO Product ID:	HA765
Status:	Prequalified
INN, dosage form and strength:	Dolutegravir (sodium) Tablet, Dispersible 10mg
Date of prequalification:	14 Dec, 2021
Basis of listing:	Prequalification - Full
Therapeutic area:	HIV/AIDS
Type:	Finished Pharmaceutical Product
Dosage form:	Tablet, Dispersible
Applicant organization:	**Macleods Pharmaceuticals Ltd** 304 Atlanta Arcade, Marol Church Road, Andheri (East) Mumbai, 400 059 India

Packaging details and storage conditions:

Packaging Type:	Bottle, HDPE
Configuration:	90x1, 30x1
Shelf life (months):	36
Storage conditions:	Do not Store above 30°C. Store in the original package to protect from moisture.

API Manufacturing Site(s)

By Organization | By Active Ingredient

Macleods Pharmaceuticals Ltd
Plot No 2209 GIDC Industrial Estate At and Post Sarigam, Taluka: Umbergaon Dist: Valsad Gujarat 396 155 India

Dolutegravir (sodium)

FPP Manufacturing Site(s)

Macleods Pharmaceuticals Ltd
Block No. N2, Village Theda, P.O. Lodhi Majra, District Solan Teh Baddi, Himachal Pradesh 174 101 India

Macleods Pharmaceuticals Ltd
Unit 2, Plot No 25-27, Survey No 366, Premier Industrial Estate, Kachigam Daman, 396 210 India

WHO Public Assessment Reports

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 strin regulatory authorities (term to be revised). The medicine may be authorised for additional or different uses by national medici regulatory authorities.*

Part 1 , Part 2 , Part 3 , Part 4 , Part 5 , Part 6 , Part 7 , Part 8