



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr T Mohan
UniPharmaceuticals (Pty) Ltd
Blue Valley Centre
Coatbridge Road
Kosmosdal
Centurion

Dear Mr Mohan

Section 21 Authorization for RIFABUTIN 150MG CAPSULES 30'S

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Rifabutin 150mg Capsules 30's**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

Batho Pele - putting people first

Section 21 Authorisation re Rifabutin 150mg Capsules 12032026-2

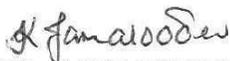
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **08 September 2026**.

Table 1: Provincial estimates

Province	Six Months Estimate
DCS	0
EC-MT	0
EC-PE	0
FS	12
GP	4 200
KZN	0
LP	0
MP	30
NC	30
NW	270
SAMHS	6
WC	0
Total	4 548

Yours sincerely



KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 16/3/2026

Section 21 Outcome Letter

2026-03-08

Ms Buhle Mbongo

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):

Your application dated **2026-03-04** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: Unipharmaceuticals (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 200**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Uni-Rifabutix 150 mg**
- G. QUANTITY: 6000 Packs (1)**

S2100023517



SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

H. LETTER NUMBER: S2100023517

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'M Moropa'.

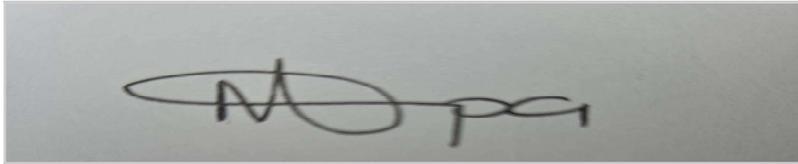
Ms Mahlodi Moropa

Final Approver

S2100023517



SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083



SALES QUOTATION

QUOTE NUMBER: UHQZ7-1704

RFQ DETAILS: S21RFQ168

DATE: 2026/02/13

CLOSING DATE: 13/03/2026

CUSTOMER VAT NO: N/A

CSD NUMBER: MAAA1624631

VAT NUMBER: 4470295637

2026/02/13

13/03/2026

N/A



Sales Dept. Yolisha

FROM

Unipharmaceuticals (PTY) LTD

PHYSICAL ADDRESS:

Office A4, 1st Floor, Blue Valley Center
Coatbridge Road
Centurion, 0157

TO:

National Department of Health

Attention: Ms. Buhle Mbongo

Email: Section21Quotes@health.gov.za

Tel: 012 395 9539

No	Description	Quantity Ordered	Unit Price Ex VAT	Unit Price Including VAT	Total Price Ex Vat	VAT Amount	Total Offer Amount (incl VAT)
1	Rifabutin Capsules USP 150 mg 4500 Boxes of 30's	4 500	R 1 158,26	R 1 332,00	R 5 212 173,91	R 781 826,09	R 5 994 000,00

Total Quantity Offered: 4500 in Total, with a delivery time landed 60 days.
Quote Validity: 30 Days

Total	R	5 212 173,91
Total VAT:	R	781 826,09
Grand Total:	R	5 994 000,00

Banking Details:

Bank: Standard Bank of South Africa Limited
Account Name: Unipharmaceuticals (Pty) Ltd.
Account Number: 242786359
Branch Code: 051001
Swift Code: SBZAZAJJ Branch Name: Midrand, South Africa.



Unipharmaceuticals (Pty) Ltd

Registration No:2020/566329/07 | Vat: 4470295637

Office A4, 1st Floor, Blue Valley Centre, Coatbridge Road, Kosmosdal, Centurion, 0157, South Africa

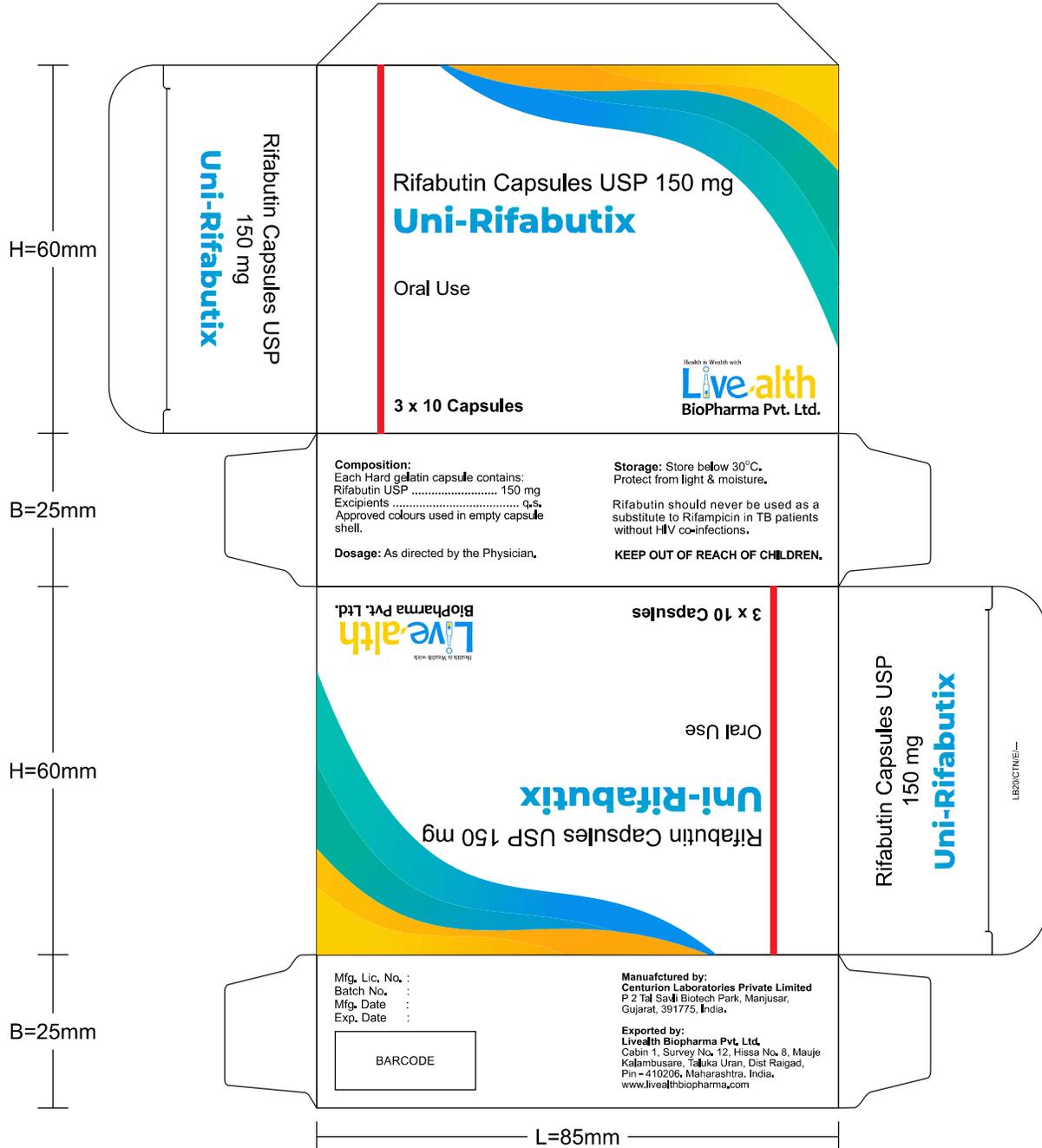
Tel: +27 (0) 11 318 2110 | Fax: +27 (0) 11 318 2965 | E: pharmacist@unipharmaceuticals.co.za

Directors: Z Hansa & T Mohan

Into Africa - for Africans - who understand the African landscape

Rifabutin Capsules USP 150 mg

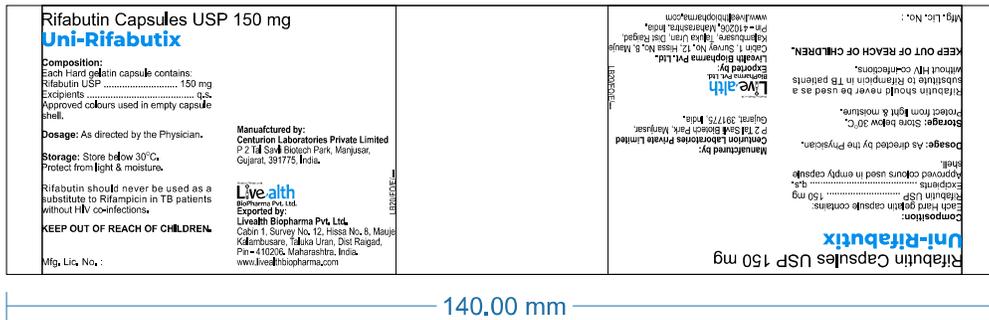
Carton Size: L=85 x B=25 x H=60 mm



Product Name	: Uni-Rifabutin	Colour Scheme	Prepared By :			Proof 1:								
Material / Pack	: Carton	<table border="1"> <tr><td></td><td>C</td></tr> <tr><td></td><td>M</td></tr> <tr><td></td><td>Y</td></tr> <tr><td></td><td>K</td></tr> </table>		C			M		Y		K	Name	Signature	Date
	C													
	M													
	Y													
	K													
Design Style	:			09/02/26										
Dimensions (mm)	: L=85xB=25xH=60		Approved By: Signature / Date											
Artwork Code	: LB20/CTN/E/---		Marketing:	Production:										
Coating / Lamination	:													
Final Date	:	PANTONE:	DRA:	QC:	QA Approval:									
Remarks	:	PANTONE:												

Rifabutin Capsules USP 150 mg

Foil Size: 140 mm (2 Track)



Rifabutin Capsules USP 150 mg
Uni-Rifabutix

Composition:
 Each Hard gelatin capsule contains:
 Rifabutin USP 150 mg
 Excipients q.s.
 Approved colours used in empty capsule shell.

Dosage: As directed by the Physician.

Storage: Store below 30°C.
 Protect from light & moisture.

Rifabutin should never be used as a substitute to Rifampicin in TB patients without HIV co-infections.

KEEP OUT OF REACH OF CHILDREN.

Mfg. Lic. No. :

Manufactured by:
Centurion Laboratories Private Limited
 P 2 Tal Savli Biotech Park, Manjusar,
 Gujarat, 391775, India.

Livealth
 BioPharma Pvt. Ltd.
Exported by:
 Livealth Biopharma Pvt. Ltd.
 Cabin 1, Survey No. 12, Hissa No. 8, Mauje
 Kalambusare, Taluka Uran, Dist Raigad,
 Pin - 410206, Maharashtra, India.
 www.livealthbiopharma.com

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Final Date	:	PANTONE:											
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