



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 Extension 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 Extension Authorisation re Rifabutin 150mg Capsules 01092026

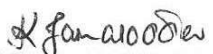
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled 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 **21 February 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate	Uptake
Correctional Services	0	0
EC-MT	0	200
EC-PE	0	
FS	12	0
GP	4 200	50
KZN	0	0
LP	0	0
MP	30	0
NC	30	0
NW	270	250
SAMHS	6	0
WC	0	750
Total	4 548	1 250

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 01/09/2026

Section 21 Outcome Letter

2026-09-01

Ms Khadija Jamaloodien

Dr AB Xuma, National Department Of Health, Voortrekker Road, Pretoria Townlands 351-Jr,
Pretoria, South Africa, Voortrekker Road, Thaba Tshwane, Pretoria, Gauteng, Gauteng, South
Africa, 0157

Pretoria, Gauteng

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

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 **2026-08-21** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Khadija Jamaloodien**
- C. IMPORTING COMPANY: Unipharmaceuticals (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 1**
- E. UNREGISTERED MEDICINES: GENERIC NAME (INN / ACTIVE INGREDIENT):
Rifabutin**
- F. TRADE NAME: Uni-Rifabutix 150 mg**

G. QUANTITY: 3300 Packs (30)

H. LETTER NUMBER: S2100036037

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:

No Data

Yours faithfully,

Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in blue ink. The signature is cursive and appears to read 'Shyamli Munbodh'.



health

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0187 Tel (012) 395 8000, Fax (012) 395 8918

REQUEST FOR QUOTATION FORM

- **Instruction to complete this Request for Quotation (RFQ)**
PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).
PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.
THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.
- **THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS. IT MAY ALSO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED

REFERENCE NUMBER:	NORMAL		SECTION 21	X	S21RFQ168
QUOTE ENQUIRY DATE	04/02/2026	QUOTE CLOSING DATE			15/02/2026
FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE (SCM Practitioner to Specify if applicable)					
<u>REQUESTING INSTITUTION CONTACT DETAILS</u>					
NAME OF REQUESTOR	Buhle Mbongo				
EMAIL ADDRESS	Buhle.Mbongo@health.gov.za				
PHONE No.	012 395 9539	FAX No.	N/A		
<u>PRODUCT INFORMATION</u>					
DESCRIPTION PER MPC	RIFABUTIN 150MG CAPSULES 30'S				
TRADE DESCRIPTION	Uni-Rifabutix 150mg				
UNIT OF MEASURE	30's	PACK or BOX (<i>SIZE/ QUANTITY</i>)			30's
QUANTITY REQUIRED	4 500 x 30's				
<u>TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER</u>					
<u>SUPPLIER CONTACT DETAILS (as per CSD)</u>					
COMPANY NAME	Unipharmaceuticals (PTY) Ltd				
SUPPLIER NUMBER	MAAA1624631				
SUPPLIER CODE (NDoH)					
CONTACT PERSON 1	NAME	Mr Theren Mohan			
	PHONE	011 3182110	FAX		
	MOBILE	0724362055			
	E-MAIL	therenm@unipharmaceuticals.co.za			
CONTACT PERSON 2	NAME	Ms. Preeta Jekison			
	PHONE	011 318 2110			
	MOBILE	0822920021			

	E-MAIL	pharmacist@unipharmaceuticals.co.za
QUOTE DETAILS		
PRICE PER BOX (INCL. VAT)	R 1 158.26	TOTAL PRICE (INCL. DELIVERY & VAT) R 5994 000.00
*STOCK'S EXPIRY DATE(SHELF-LIFE)	Approximately 22 - 24 months	
VOLUMES AVAILABLE – 7DAYS		
VOLUMES AVAILABLE – 14DAYS		
VOLUMES AVAILABLE – 21DAYS		
VOLUMES AVAILABLE – 28DAYS		
VOLUMES AVAILABLE – 35DAYS		
VOLUMES AVAILABLE - 42DAYS		
VOLUMES AVAILABLE – 49DAYS		
VOLUMES AVAILABLE – 56DAYS		
VOLUMES AVAILABLE – 112DAYS	100% of stock landed in 60 days	
QUOTE VALIDITY PERIOD	Valid for 30 days	
NORMAL LEAD/DELIVERY TIME	60 days	
DEVIATION TO SPECIFICATION		
COMMENTS: N/A		
DECLARATION BY SUPPLIER		
I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.		
NAME	Mr Theren Mohan	
CAPACITY	Head of Pharma	
SIGNATURE (OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)		
DATE	13/02/2026	
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	

Please ensure that you include the following as part of the Quotation:

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Quotation on Official Company Letterhead
- Central Supplier Database Summary Report (CSD), updated for the current month
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)

All the above is required to expedite the process of reviewing the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

NB:

- *The supplier submitting the quotation must be the same entity with which the provinces will place their orders.
- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (*only in cases of a Bivalent Oral Poliomyelitis Vaccine RFQ*).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing required documentation shall not be considered.
- Any submission with blurry required documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION

National Department of Health
Attention: Ms. Buhle Mbongo
Email: Section21Quotes@health.gov.za
Tel: 012 395 9539

13th February 2026

Re: Response to S21RFQ168 Rifabutin 150mg Capsules 30's

Dear Buhle Mbongo

We trust this email finds you well. Please find below & attached Unipharmaceuticals offer, with a supplier code of **MAAA1624631**, response for **S21RFQ168 Rifabutin 150mg Capsules 30's** to be supplied under section 21 terms to the National Department of Health, in South Africa (SA).

Product Details:

- Generic Name: **Rifabutin 150mg Capsules 30's**
- Trade Name: **Uni-Rifabutix 150mg**
- Country of Origin: **India.**
- Manufacturer: **Centurion Laboratories Private Limited.**
- Total Quantity Offered: 4500 boxes in Total, with a **delivery time landed 60 days.**
- Packed: **Box of 30's (3 x 10C)**

Offer Box delivered to Provincial Pharmaceutical Depots in SA:

Unit Price (per box of 30's) Ex Vat	R 1,158.26
Unit Price Including Vat	R 1,332.00
Total Boxes	4500 boxes of 30's (3 X 10C)
Total Price ex vat	R 5 212 173.91
Vat	R 781 826.09
Total Price Including Vat	R 5 994 000.00

Please find attached the following documentation:

- Unipharmaceuticals Quote
- Section 21 Completed form
- GMP Manufacturer Certificate, Package Insert & Label / Artwork

We look forward to your response and please feel free to reach out should you have any questions.

Kind regards



Mr. Theren Mohan
Head of Unipharmaceuticals (Pty) Ltd

Unipharmaceuticals (Pty) Ltd

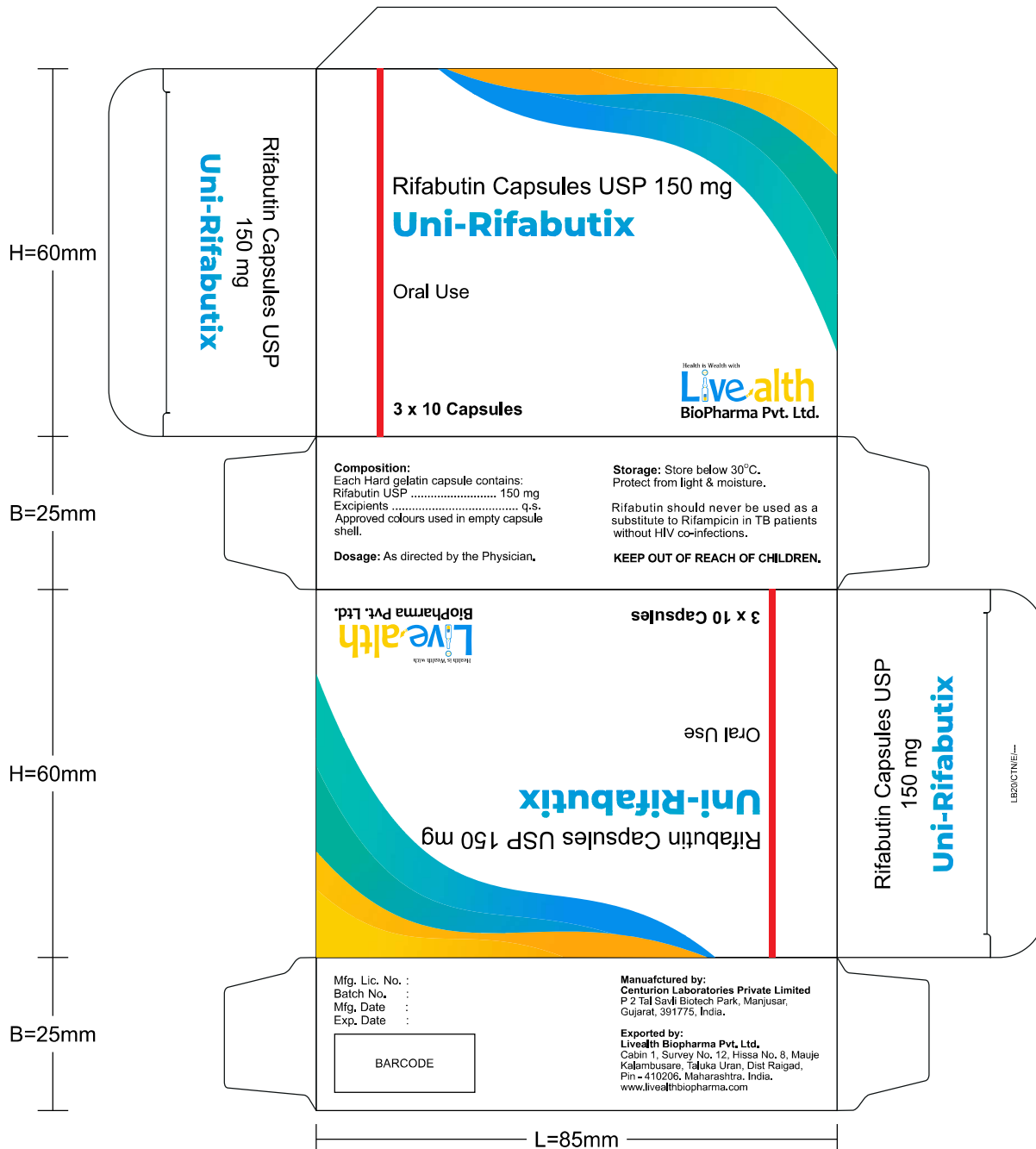


Registration No:2020/566329/07 | Vat: 4470295637
Office A4, 1st Floor, Blue Valley Centre, Coatbridge Road, Kosmosdal, Centurion, 0157, South Africa
Tel: +27 (0) 11 318 2110 | Fax: +27 (0) 11 318 2965 | E: pharmacist@unipharmaceuticals.co.za
Directors: Z Hansa & T Mohan

Into Africa- for Africa- by 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-Rifabutix	Colour Scheme		Prepared By :			Proof 1:
Material / Pack	:	Carton	C M Y K	Name	Signature	Date		
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. Live-alth 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	Mfg. Lic. No. : Uni-Rifabutix Rifabutin Capsules USP 150 mg 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. :
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140.00 mm

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. Live-alth 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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Product Name	: Uni-Rifabutix	Colour Scheme	Prepared By :	Proof 1:
Material / Pack	: Foil		Name	Signature
Design Style	:			Date
Dimensions (mm)	: 140 mm		Approved By: Signature / Date	
Artwork Code	: LB20/FO/E/---		Marketing:	Production:
Coating / Lamination	:			
Final Date	:	PANTONE:	DRA:	QC:
Remarks	:	PANTONE:		QA Approval:

Rifabutin Capsules USP 150 mg

Insert Size: L=180 mm x H=180 mm

L=180.00 mm

Rifabutin Capsules USP 150 mg

Uni-Rifabutix

COMPOSITION:
Each Hard gelatin capsule contains:
Rifabutin USP 150 mg
Excipients 150 mg
Total weight 300 mg
Approved colors used in empty capsule shell.

PHARMACEUTICAL FORM: Hard Gelatin Capsule

THERAPEUTIC INDICATIONS:

Rifabutin is indicated for:
- The prophylaxis of *M. avium* intracellular complex (MAC) infections in patients with HIV disease with CD4 counts lower than 75 cells/mm³.
- The treatment of non-tuberculous mycobacterial disease (such as that caused by MAC and *M. avium*).
- Primary tuberculosis.

PHARMACOLOGICAL PROPERTIES:
Pharmaco-therapeutic group: Antibiotics
ATC code: J04B04

Pharmacodynamics:
Rifabutin is a rapidly absorbed and maximum plasma concentrations are expected around 2-4 hours after oral administration. The pharmacokinetics of rifabutin is linear after single administration of 300, 450, and 600 mg to healthy volunteers. With these doses, C_{max} is in the range of 0.4-0.7 µg/ml. Plasma concentrations are maintained above the MIC values for *M. tuberculosis* up to about 30 hours from administration.

Distribution
Rifabutin is widely distributed in various animal organs with the exception of the brain. In particular, in human lung tissue the concentrations measured up to 24 hours after dosing were about 5-10 times higher than the plasma levels.
The intracellular penetration of rifabutin is very high as demonstrated by intracellular/extracellular concentration ratios which ranged from 9 in neutrophils to 15 in monocytes, both obtained from human subjects. Rifabutin is highly active against intracellular pathogens including *M. tuberculosis* and against intracellular pathogens such as mycobacteria.

Elimination
Rifabutin and its metabolites are eliminated mainly by the urinary route. The T_{1/2} of rifabutin in man is approximately 35-40 hours.

CONTRAINDICATIONS:
Hypersensitivity or history of hypersensitivity to the active substance, other rifamycins (e.g., rifampicin) or any of the excipients.
Concomitant use with rifavirine containing protease-inhibase suspension for injection is contraindicated.
Due to insufficient clinical experience in pregnant and breast-feeding women and in children, rifabutin should not be used in these patients.

POSLOGY AND METHOD OF ADMINISTRATION:
This medicine can be administered as a single daily oral dose at any time independently of meals.

Adults
Prophylaxis of *M. avium* intracellular complex (MAC) infections in patients with HIV disease with CD4 counts lower than 75 cells/mm³:
- 300 mg (2 capsules) as a single agent.

Treatment of non-tuberculous mycobacterial disease:
- 450-600 mg (3-4 capsules) in combination regimens for up to 6 months after negative cultures are obtained.
- Rifabutin is given in association with clarithromycin (or other macrolides) and/or isoniazide (or rifampicin). The rifabutin dose may need to be reduced to 300 mg.

Treatment of pulmonary tuberculosis:
- 150-450 mg (1-3 capsules) in combination regimens for at least 6 months.
In accordance with the commonly accepted criteria for the treatment of mycobacterial infections, rifabutin should always be given in combination with other anti-mycobacterial drugs not belonging to the family of rifamycins.

Paediatrics
There are inadequate data to support the use of this medicine in children at the present time.

Elderly
No specific recommendations for dosage alterations in the elderly are suggested.

WARNING AND PRECAUTIONS:

Patients should be assessed to ensure that they do not have active disease caused by pulmonary tuberculosis or other mycobacteria.
Rifabutin may impair a red-orange colour to the urine and possibly to skin and body secretions. Contact lenses, especially soft, may be permanently stained.
Mild hepatic impairment does not require a dose modification. Rifabutin should be used with caution in patients with severe liver insufficiency. Mild to moderate renal impairment does not require any dosage adjustment.
Severe renal impairment (creatinine clearance below 30 ml/min) requires a dosage reduction of 50%. It is recommended that white blood cell and platelet counts and liver enzymes be monitored periodically during treatment.

Because of the possibility of occurrence of uveitis, patients should be carefully monitored when rifabutin is given in combination with protease inhibitors and zidovudine. Patients should be advised to report any visual complaints. If such an event occurs, the patient should be referred to an ophthalmologist and, if considered necessary, rifabutin treatment should be suspended.

Uveitis associated with rifabutin must be distinguished from other ocular complications of HIV.
HIV protease inhibitors act as substrates or inhibitors of CYP450 3A4 mediated metabolism. Therefore, due to significant drug-drug interactions between protease inhibitors and rifabutin, their concomitant use with rifabutin is not recommended.
Rifabutin is a CYP450 3A4 inducer. Therefore, co-administration with antiretroviral medicines including but not limited to zalcitabine, didanosine, zalcitabine, or zalcitabine and antiretroviral medicines including but not limited to zalcitabine (alone or in combination) is not recommended due to the expected decrease in plasma concentrations of the antiretroviral and anti-HIV medicines which may lead to loss of virologic response and possible development of resistance.

For further recommendations, please refer to the most recent prescribing information of the antiretroviral medicines.

Clostridium difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including rifabutin, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.
C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality as these infections can be refractory to therapy and may result in colonic perforation.

CDAD has been reported with the use of rifabutin. If CDAD is suspected or confirmed, appropriate measures to identify and manage the disease should be initiated. A CDAD risk assessment should be considered prior to the administration of antibacterials.

There have been reports of severe cutaneous adverse reactions (SCARs), such as Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) with anti-tuberculous drugs. Identifying the specific drug is difficult, as multiple anti-tuberculous drugs are prescribed in association concurrently. Specifically, for DRESS, a multi-system potential life-threatening SCAR, time to onset of the first symptoms may be prolonged. DRESS is a clinical diagnosis, and its clinical presentation remains the basis for decision making. An early withdrawal of the suspect drug is essential because of the syndrome's morbidity and visceral involvement (e.g., liver, bone marrow or kidney).

DRUG INTERACTIONS:

Rifabutin has been shown to induce the enzymes of the cytochrome P450 3A (CYP450 3A) subfamily

and therefore may affect the pharmacokinetic behaviour of drugs metabolised by the enzymes belonging to this subfamily. Upward adjustment of the dosage of such drugs may be required when administered with rifabutin.
Similarly, rifabutin might reduce the activity of analgesics, anticonvulsants, corticosteroids, cyclosporin, digoxin (although not digoxin), oral hypoglycaemics, narcotics, phenytoin and quinidine.
Clinical studies have shown that rifabutin does not affect the pharmacokinetics of didanosine (DDI), and is considered (however, for the latter refer also to undesirable effects). On the basis of the above metabolic considerations no significant interaction may be expected with efavirenz, theophylline, zalcitabine, zalcitabine (DDI), zalcitabine and zalcitabine (DDI).

Patients should be advised to inform their physician if they are taking any other drugs, especially when rifabutin and rifabutin are both to be administered together (see below) in combination with other anti-mycobacterial drugs not belonging to the co-administered drug, and risk-benefit statement.

PREGNANCY AND LACTATION:

Due to lack of data in pregnant women, as a precautionary measure, rifabutin should not be administered to pregnant women or those breast-feeding children even though in experimental animal studies the drug was not teratogenic.

Rifabutin may interact with oral contraceptives.

ADVERSE EFFECTS:

The tolerability of rifabutin in multiple drug regimens, was assessed in both immunocompetent and immunocompromised patients. In clinical studies, the most frequent adverse effects were mycobacteriosis in long term studies with rifabutin doses up to 600 mg.
Bearing in mind that rifabutin was often given in these studies as part of a multiple drug regimen it is not always possible to define with certainty a drug-event relationship. Treatment discontinuation was necessary only in a very few cases. Adverse reactions identified through clinical trials or post-marketing surveillance by system organ class (SOC) are listed below in the following frequencies:
very common ≥1/100 to < 1/10; uncommon ≥1/1,000 to < 1/100; rare ≥1/10,000 to < 1/1,000; very rare <1/10,000 and not known.

MedDRA System Organ Class	Frequency	Undesirable Effects
Blood and lymphatic system disorders	Very common	Leukopenia
	Common	Anaemia
	Uncommon	Pancytopenia Agranulocytosis Lymphopenia Neutropenia Neutrophilia White blood cell count decreased Neutrophil count decreased Thrombocytopenia Platelet count decreased
Immune system disorders	Common	Rash
	Uncommon	Hypersensitivity Bronchospasm Eosinophilia
Eye disorders	Uncommon	Uveitis Corneal deposits
Gastrointestinal disorders	Common	Nausea
	Uncommon	Vomiting
Hepatobiliary disorders	Uncommon	Jaundice Hepatic enzyme increased
Skin and subcutaneous tissue disorders	Uncommon	Skin discoloration
Musculoskeletal and connective tissue disorders	Common	Myalgia
	Uncommon	Arthralgia
General disorders and administration site conditions	Common	Pyrexia

Clostridium difficile colitis is a mandated adverse reaction for the pharmacological class; this event was added to the summary. Upward adjustment of the dosage of such drugs may be required when administered with rifabutin.
Anaphylactic shock has occurred with other antibiotics of the group.
Mild to severe, reversible uveitis has been reported less frequently when rifabutin is used at 300 mg as monotherapy in MAC prophylaxis, versus rifabutin in combination with clarithromycin (or other macrolides) for MAC treatment.
H-like syndrome, chest pressure or pain with dyspnoea and rarely hepatitis and haemolysis has been reported.

Anti-tuberculous drug SCARs.

Anti-tuberculous drug use may lead to the occurrence of drug reaction with eosinophilia and systemic symptoms (DRESS) as well as other SCARs such as SJS, TEN, and AGEP.

OVERDOSE:

Clinical data on overdosage are limited. In case of overdosage, supportive care and symptomatic treatment should be administered.

PRESENTATION:

3 x 10 capsules packed in a printed carton along with an insert.

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

KEEP OUT OF REACH OF CHILDREN.

Manufactured by:
Centurion Laboratories Private Limited
Plot No. 3, Sector 10, Gurgaon Park, Manesar,
Gujarat, 391775, India.

Exported by:
BioPharma Pvt. Ltd.
BioPharma Pvt. Ltd.
Cabin 1, Survey No. 12, Hessa No. 8, Majura
Kalamassare, Taluka Uran, Dist Raigad,
Pin - 410506, Maharashtra, India.
www.centurionlabpharmazone.com



CSD REGISTRATION REPORT

SUPPLIER IDENTIFICATION

Supplier number	MAAA1624631	Total annual turnover	R10 million or less; or
Is supplier active?	Yes	Financial year start date	01 Mar 2021 00:00:00:000
Supplier type	CIPC Company	Registration date	22 Jul 2020 00:00:00:000
Supplier sub-type	Private Company (Pty)(Ltd)	Created by	pharmacist@unipharmaceuticals.co.za
Legal name	UNIPHARMACEUTICALS	Created date	17 Jul 2025 08:59:13:000
Identification type	South African Company/Close Corporation Registration Number	Edit by	csd.reverifbybatch@treasury.gov.za
Government breakdown	Private Companies (Pty) (Ltd)	Edit date	23 Jan 2026 10:49:03:253
Business status	In Business	Restricted Supplier	No
Country of origin	South Africa	Restricted Director	No
South African company/CC registration number	2020/566329/07	Government Employee	No
Have Bank Account	Yes		

SUPPLIER INDUSTRY CLASSIFICATION INFORMATION

INDUSTRY CLASSIFICATION 1

Main group	Manufacturing		
		Core industry	Manufacture of basic pharmaceutical products and pharmaceutical preparations
Division	Manufacture of basic pharmaceutical products and pharmaceutical preparations	% share of annual turnover	60.00

INDUSTRY CLASSIFICATION 2

Main group	Administrative and support activities		
Division	Office administrative, office support and other business support activities	% share of annual turnover	40.00

SUPPLIER CONTACT INFORMATION

CONTACT 1

Contact type	Bid Office	Cellphone number	082 292 0021
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CSD REGISTRATION REPORT

Is this your preferred Contact?	Yes	Do you want this contact to also be a CSD user ?	Yes
Name(s)	Preeta	Created by	pharmacist@unipharmaceuticals.co.za
Surname	Jekison	Created date	17 Jul 2025 08:59:20:047
Identification type	South African Identification Number	Edit by	csd.datafix@treasury.gov.za
Prefer communication via email	Yes	Edit date	17 Jul 2025 08:59:20:047
Email address	pharmacist@unipharmaceuticals.co.za		

SUPPLIER ADDRESS INFORMATION

ADDRESS 1

Is this a preferred address?	Yes	Postal code	0157
Address line 1	OFFICE A4 1ST FLOOR BLUE VALLEY CE	Ward Number	77
Address line 2	RIETSPRUIT ROAD	Country	South Africa
Suburb	Blue Valley Golf Estate	Created by	pharmacist@unipharmaceuticals.co.za
Province	Gauteng	Created date	17 Jul 2025 08:59:19:827
Municipality	City of Tshwane	Edit by	pharmacist@unipharmaceuticals.co.za
City	Centurion	Edit date	17 Jul 2025 08:59:19:827

ADDRESS 2

Is this a preferred address?	No	Postal code	0157
Address line 1	OFFICE A4 1ST FLOOR BLUE VALLEY CE	Ward Number	77
Address line 2	RIETSPRUIT ROAD	Country	South Africa
Suburb	Blue Valley Golf Estate	Created by	pharmacist@unipharmaceuticals.co.za
Province	Gauteng	Created date	17 Jul 2025 08:59:20:017
Municipality	City of Tshwane	Edit by	pharmacist@unipharmaceuticals.co.za
City	Centurion	Edit date	17 Jul 2025 08:59:20:017

SUPPLIER BANK ACCOUNT

BANK ACCOUNT 1

Account type	Current Accounts	Created date	05 Dec 2025 10:35:10:000
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CSD REGISTRATION REPORT

Bank	STANDARD BANK OF SOUTH AFRICA	Edit by	csd.safetynetbatchdownload@treasury.gov.za
Branch number	051001	Edit date	08 Dec 2025 09:00:26:157
Branch name	STANDARD BANK SOUTH AFRICA	Bank Verification Status	Verification Succeeded
Account number	242786359	Foreign Bank Account	No
Account holder	UNIPHARMACEUTICALS PTY LTD	Is the identifier linked at the bank	Yes
Is this a preferred account?	Yes	Is this a Shared Funding Account	No
Active start date	07 Jul 2025 09:08:26:000	Funding Partner(s)	
Created by	pharmacist@unipharmaceuticals.co.za		

TAX INFORMATION

Income tax number	9230808249	Overall Tax Status	Tax Compliant
VAT number	4470295637	Tax compliance status pin provided	Yes
Is this supplier a VAT vendor?	Yes	Created by	pharmacist@unipharmaceuticals.co.za
PAYE number	7660812712	Created date	17 Jul 2025 08:59:22:093
Are you Registered with SARS?	Yes	Edit by	csd.reverifibatch@treasury.gov.za
Last validation date	11 Feb 2026 18:15:00:000	Edit date	23 Jan 2026 10:49:03:000
Would you like to receive notifications?	Yes		

ACCREDITATION INFORMATION

ACCREDITATION 1

Accreditation body	SAHPRA - South African Health Products Regulatory Authority	Created by	pharmacist@unipharmaceuticals.co.za
Accreditation number	1455.-2	Created date	17 Jul 2025 08:59:25:633
Assesment Date	31 Jan 2024 00:00:00:000	Edit by	pharmacist@unipharmaceuticals.co.za
Expiry date	31 Jan 2029 00:00:00:000	Edit date	17 Jul 2025 08:59:25:633
Accreditation status	Active	Verification status	Manual verification required
Description	Licence to Manufacture medicines		

B-BBEE INFORMATION



CSD REGISTRATION REPORT

Are you an empowering supplier	No	Accept and understand the content of the affidavit	Yes
% Owned by black people	80.00	Commissioner of Oath	South African Police Service
% Owned by black people who are women	60.00	Date affidavit signed by commissioner of oath	01 Dec 2025 00:00:00:000
% Owned by black people who are youth	0.00	Affidavit expiry date	30 Nov 2026 00:00:00:000
% Owned by black people with disabilities	0.00	Created by	pharmacist@unipharmaceuticals.co.za
% Owned by black who are unemployed	0.00	Created date	17 Jul 2025 08:59:25:653
% Owned by black people who are military veteran	0.00	Edit by	pharmacist@unipharmaceuticals.co.za
% Owned by black people living in rural or underdeveloped areas	0.00	Edit date	03 Dec 2025 11:50:56:073
Status	Active	Verification Status	Manual Verification Required

OWNERSHIP INFORMATION

CSD can only verify the youth category of persons for South African citizens. It is the responsibility of an organ of state supply chain practitioner to obtain supporting documentation to verify the ownership information of this supplier.

Owner s name and surname Legal name	Owner s Identification number	RSA Citizen	Ethnic group	Gender	Ownership %	Youth	Disabled	Military	Rural	Township
THEREN MOHAN	8001135150084	Yes	Indian	Male	20.00%	No	No	No	No	No
ZIBYA HANSA	7808170128085	Yes	Coloured	Female	60.00%	No	No	No	No	No
LEANNE BLUMENTHAL	6409290197083	Yes	White	Female	20.00%	No	No	No	No	No
Total					100.00%					

CATEGORY OF PERSONS BASED ON OWNERSHIP

Owned by black people	80.00%
Owned by black people who are women	60.00%
Owned by people	100.00%
Owned by people who are women	80.00%

DIRECTORS /MEMBERS / OWNERS INFORMATION

DIRECTOR/MEMBER 1

Director type	Director,Owner	Owner youth	No
Director status	Active	Owner person with disabilities	No
Name(s)	THEREN	Owner military veteran	No



CSD REGISTRATION REPORT

Surname	MOHAN	Created by	pharmacist@unipharmaceuticals.co.za
Country	South Africa	Created date	27 Jun 2025 09:58:03:000
Identification type	South African Identification Number	Edit by	pharmacist@unipharmaceuticals.co.za
South African identification number	8001135150084	Edit date	03 Dec 2025 11:50:46:000
Work permit	0000000	Restricted Director	No
Appointment date	04 Oct 2021 00:00:00:000	Restriction Last Verification Date	11 Feb 2026 18:15:00:447
Email address	THERENM@UNIPHARMACEUTICALS.CO.ZA	Government Employee	No
Cellphone number	0724362055	Government Employee Last Verification Date	11 Feb 2026 18:15:00:273
Owner	Yes	SA identification number Verified	Yes
Ownership %	20.00%	SA identification number verification date	11 Feb 2026 18:15:00:337
Owner's ethnic group	Indian	Ownership verification status	Verified by CIPC
Owner's gender	Male	Ownership last verification date	01 Jan 1900 00:00:00:000

DIRECTOR/MEMBER 2

Director type	Director, Owner	Owner's gender	Female
Director status	Active	Owner youth	No
Name(s)	ZIBYA	Owner person with disabilities	No
Surname	HANSA	Owner military veteran	No
Country	South Africa	Created by	pharmacist@unipharmaceuticals.co.za
Identification type	South African Identification Number	Created date	27 Jun 2025 09:58:04:000
South African identification number	7808170128085	Edit by	pharmacist@unipharmaceuticals.co.za
Work permit	0000000	Edit date	03 Dec 2025 11:50:49:000
Appointment date	04 Oct 2021 00:00:00:000	Restricted Director	No
Email address	ZIBYAH@UNICORE.CO.ZA	Restriction Last Verification Date	11 Feb 2026 18:15:00:447
Cellphone number	0664687504	Government Employee	No
Owner	Yes	Government Employee Last Verification Date	11 Feb 2026 18:15:00:290
Ownership %	60.00%	SA identification number Verified	Yes
Living areas of owner	City of Tshwane, Southdowns Irene Country Farm	SA identification number verification date	11 Feb 2026 18:15:00:350
Owner's ethnic group	Coloured	Ownership verification status	Verified by CIPC
		Ownership last verification date	01 Jan 1900 00:00:00:000



CSD REGISTRATION REPORT

DIRECTOR/MEMBER 3

Director type	Owner
Director status	Active
Name(s)	LEANNE
Surname	BLUMENTHAL
Country	South Africa
Identification type	South African Identification Number
South African identification number	6409290197083
Appointment date	03 Dec 2025 00:00:00:000
Email address	regulatory@unipharmaceuticals.co.za
Cellphone number	082 600 5445
Owner	Yes
Ownership %	20.00%
Living areas of owner	City of Johannesburg, Abbotsford
Owner's ethnic group	White
Owner's gender	Female
Owner youth	No

Companies involved in

MAAA1069989; MAAA1088668;
MAAA1111243; MAAA1113192;

Owner person with disabilities	No
Owner military veteran	No
Created by	pharmacist@unipharmaceuticals.co.za
Created date	27 Jun 2025 10:11:43:000
Edit by	pharmacist@unipharmaceuticals.co.za
Edit date	03 Dec 2025 11:38:45:000
Restricted Director	No
Restriction Last Verification Date	11 Feb 2026 18:15:00:460
Government Employee	No
Government Employee Last Verification Date	11 Feb 2026 18:15:00:290
SA identification number Verified	Yes
SA identification number verification date	11 Feb 2026 18:15:00:383
Ownership verification status	Verified by CIPC
Ownership last verification date	01 Jan 1900 00:00:00:000

Tips and Frequently Asked Questions (FAQ)



CSD REGISTRATION REPORT

Identifier

CSD cannot electronically verify the identity of a supplier other than a South African Individual / Sole Proprietor (through Home Affairs) or a company registered at the Companies and Intellectual Property Commission (CIPC). For this reason, a disclaimer is displayed for supply chain practitioners to obtain supporting documentation to verify the identity and legitimacy of a supplier in these cases.

Bank

For help on how to resolve bank failures click here: [I received an email stating the bank information I captured on the CSD was sent for bank account validation and could not be validated. The response received from the bank contains an error message.](#)

The various possible error messages received from the bank are highSemiBolded in red. Search for the applicable message and follow the detailed steps associated with that error message.

Tax

Tax Compliance Status

For help on how to deal with tax status differences between CSD and the tax clearance certificate click here: [What should a supplier do if the tax status on CSD difference from the tax clearance certificate?](#)

Tax Compliance Expiry Date

For help on how to deal with tax status differences between CSD and the tax clearance certificate click here: [How does CSD determine the tax compliance expiry date?](#)

CIPC

Should the director/member information reflected on the CIPC registration report differs to that reflected on CSD for help click here: [The active Directors/Members are not being populated on the CSD Directors/Members screen as they appear at CIPC. how can I rectify this?](#)

State Employee

For more information pertaining to government employment status click here: [Will there be verification done to identify if a supplier is a government employee?](#)

BBBEE

CSD does not automatically verify all certificate information with the various accreditation bodies. Organs of State are required, where not automatically verified by CSD, to manually verify this information with the applicable accreditation body as per current policies and procedures. Expired certificate information do not reflect on the report.

RESTRICTION

Restricted Supplier - A supplier is restricted by using the identification number of the entity e.g. CIPC registration -, trust -, Social Development non-profit -, South African ID -, Foreign company registration number or ID number. If there is more than one CSD Supplier profile registered on CSD with the same entity identification number, all those related supplier profiles will be restricted.

Restricted Director - A director/owner is an individual person and is restricted by using the South African ID or Foreign ID number. If a director belongs to different companies and has been restricted, the director will reflect as restricted in all companies where identification number is detected.

Restricted Suppliers & Directors are listed on CSD under Help - [Am I restricted?](#)

The CSD does not automatically verify foreign company registration number, international securities identification number, foreign identification numbers, foreign passport numbers, work permit numbers, foreign bank accounts, B-BBEE, demographic and accreditation information. Organs of State are required to manually verify this information with the applicable verification institutions as per their current policies and procedures.





CSD REGISTRATION REPORT

Print Date:

2/11/2026 6:15:26 PM

