



Enquiries:
Stock queries:
Ms Babalwa Melitafa
E-mail: Babalwa.Melitafa@health.gov.za

Clinical queries:
Essential Drugs Programme
E-mail : SAEDP@health.gov.za

NOTICE: SUPPLY CONSTRAINTS WITH RIFABUTIN 150mg CAPSULES FOR TUBERCULOSIS (TB) TREATMENT - INTERIM THERAPEUTIC ALTERNATIVES

The Primary Healthcare (PHC) and Adult Hospital Level (AHL) Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) currently recommend the use of rifabutin 150mg capsules for select indications in the management of TB disease and mycobacterium avium complex infection. There is a reported supply constraint with rifabutin 150mg capsules.

The Affordable Medicines Directorate has initiated the process for bulk Section 21 approval. Until such time that oral rifabutin can be procured through the Section 21 process, interim guidance for managing supply constraints in the short to medium term is included below as alternatives for the respective EML indications of rifabutin:

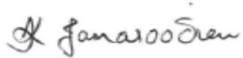
STG Indications	STG Recommendation	Interim Alternative
<p><u>PHC STGs and EML</u> Ch 11: HIV and AIDS Section 11.1 Antiretroviral therapy, adults and adolescents (≥ 15 years) – ART interactions with rifampicin Patients on atazanavir or darunavir, or if double dose LPV/r is not tolerated</p> <p><u>AHL STGs and EML</u> Ch 10: HIV and AIDS Section 10.1 Antiretroviral therapy - interactions with rifampicin Patients on atazanavir or darunavir, or if double dose LPV/r is not tolerated</p>	<p>Replace rifampicin with:</p> <ul style="list-style-type: none"> • Rifabutin, oral, 150 mg daily (<i>doctor prescribed</i>). ○ Monitor FBC monthly for anaemia and neutropenia. ○ Monitor clinically for symptoms of uveitis (e.g. pain, photophobia, variable loss of vision, circumcilliary injection, a miotic pupil) – immediately stop rifabutin pending ophthalmology opinion. 	<p>HIV-Positive Patients: Evaluate all patients for eligibility to switch to dolutegravir-containing regimen.</p> <p>In patients whose ART cannot be switched to a regimen that does not contain atazanavir or darunavir, use the 6-month TB BPaL-L treatment regimen composed of:</p> <ul style="list-style-type: none"> • bedaquiline, • pretomanid, • linezolid (600mg) • fluoroquinolone (e.g. levofloxacin) <p>Severe extra-pulmonary TB including meningitis, pericarditis, osteoarticular, abdominal or disseminated/miliary disease may not be treated with BPaL-L. Discuss all these patients with a specialist via the hotline numbers (National HIV hotline (0800 212 506) or KZN Paediatric Hotline (0800 006 603)) or the ARV Drug Resistance Committee (TLART@health.gov.za), for discussion regarding individual care.</p> <p>Monitoring for potential side effects for these agents is recommended, as outlined in the Drug-Resistant Tuberculosis Guidelines¹.</p> <p>For weight-based dosing guidance in adults and guidance on monitoring, refer to Annexure 1 of the National TB guideline: Clinical management of rifampicin-resistant tuberculosis – updated clinical reference guide (Sept 2023) – accessible online https://www.health.gov.za/wp-content/uploads/2023/10/Updated-RR-TB-Clinical-Guidelines-September-2023.pdf</p>

Note: Rifabutin does not appear in the Paediatric Hospital STGs/EML and should follow the usual referral process. Please contact the Advanced Drug Resistance Committee (TLART@health.gov.za), or the National HIV hotline (0800 212 506) or KZN Paediatric Hotline (0800 006 603), for patient-specific advice on how to manage the patient further.

Circular dissemination

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees and all other relevant stakeholders.

Kind regards



MS K JAMALOODIEN
CHIEF DIRECTOR:
SECTOR-WIDE PROCUREMENT
DATE: 18 March 2026



PROF N NDJEKA
CHIEF DIRECTOR:
TB CONTROL & MANAGEMENT
DATE: 23/03/2026