health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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NOTICE: NON-AVAILABILITY OF ETHAMBUTOL 400MG TABLETS

The availability of ethambutol 400 mg tablets is currently constrained. Although the Affordable Medicines Directorate (AMD) has identified a supplier willing to supply the tablets; deliver is only expected around mid-May 2026.

The existing ethambutol stock is due to expire at the end of April 2026. As there may be reluctance to issue medicines expiring within a month, the Cluster: Tuberculosis (TB) Control and Management in conjunction with AMD, is providing this interim guidance.

General Principles:

Regimen	Action
RHZE Initiation phase of therapy (children <25kg)	• Continue RHZ, omit ethambutol • Monitor carefully and report any new incidents of isoniazid and/or rifampicin resistance
RH phase (children <25kg)	• No modification
Non-tuberculous mycobacteria	• Discuss with a specialist

R – rifampicin, H – isoniazid, Z – pyrazinamide, E - ethambutol

NON-SEVERE TUBERCULOSIS:

Definition: Peripheral lymph node TB; intrathoracic lymph node TB without airway obstruction; uncomplicated TB pleural effusion or paucibacillary, non-cavitary pulmonary TB, confined to one lobe of the lungs, and without a miliary pattern.

CHILDREN

For children < 25kg and newly initiated on TB treatment:

Body weight (in kg)	Intensive Phase (2 months)	Continuation Phase (4 months)
	RHZ (50/75/150mg) dispersible tablets OR 50/75/150 - 4ml suspension	RH (50/75mg) dispersible tablets OR 50/75mg - 4ml suspension
<2	***Seek paediatrician guidance***	
2 – 2.9	½ tablet	½ tablet
3 – 3.9	¾ tablet	¾ tablet
4 – 7.9	1 tablet	1 tablet
8 – 11.9	2 tablets	2 tablets
12 – 15.9	3 tablets	3 tablets
16 – 24.9	4 tablets	4 tablets

For children ≥ 25kg and newly initiated on TB treatment:

- Use the adult RHZE tablet formulation.

As per Paediatric Hospital Level STGs, Chapter 10: Tuberculosis, section 10.2: Tuberculosis, Pulmonary in Children https://www.health.gov.za/wp-content/uploads/2026/03/Paediatric-STGs-and-EML-2025-2029-Review-Cycle_Updated-March-2026.pdf (Page 10.8)

For children < 25kg already initiated on ethambutol-containing TB treatment, and who have completed 2 months intensive phase treatment:

- Complete the 2–4-month continuation phase based on eligibility criteria for treatment shortening.

For children < 25kg already initiated on ethambutol-containing TB treatment, and who have not completed 2 months intensive phase treatment:

- Complete the remainder of the 2 months of intensive phase treatment with (RHZ) and proceed to 4 months of continuation phase with RH. These children are not eligible for treatment shortening.

SEVERE TB DISEASE (excluding TB meningitis and miliary TB):

Definition: Pulmonary tuberculosis with extensive or bilateral parenchymal damage, cavitary disease, tuberculous empyema, or bronchopneumonia TB; Extrapulmonary disease including spinal/ osteo-articular TB and abdominal TB; and disseminated TB.

CHILDREN

For children < 25kg and newly initiated on TB treatment:

- Intensive phase: RHZ + levofloxacin* for 2 months.
- Continuation phase: RH for 4 months or 10 months for osteoarticular TB.

**See annexure below for levofloxacin dosing chart*

For children ≥ 25kg and newly initiated on TB treatment:

- Use the adult RHZE tablet formulation.

As per Paediatric Hospital Level STGs, Chapter 10: Tuberculosis, section 10.2.2: Severe Tuberculosis Disease https://www.health.gov.za/wp-content/uploads/2026/03/Paediatric-STGs-and-EML-2025-2029-Review-Cycle_Updated-March-2026.pdf (Page 10.11)

For children <25 kg already initiated on ethambutol-containing TB treatment, and who have completed 2 months intensive phase treatment TB treatment:

- Complete the continuation phase with RH for 4 months (or 10 months for osteoarticular TB).

For children < 25kg already initiated on ethambutol-containing TB treatment, and who have not completed 2 months intensive phase treatment:

- Complete remainder of 2 months of intensive phase with (RHZ + levofloxacin) and proceed to 4 months of continuation phase with RH or 10 months for osteoarticular TB.

ADULTS

Isoniazid mono-resistant TB

Confirmed isoniazid mono-resistant TB

- RHZE at standard doses (see section 17.4.1 Pulmonary TB in adults)

AND

- Levofloxacin, oral, daily
  - 30 to 45kg: 750mg
  - ≥46kg: 1000mg

Duration: At least 6 months

Confirmed isoniazid mono-resistant TB and contraindication to isoniazid

- Rifampicin, oral, 10mg/kg daily

AND

- Pyrazinamide, oral, 25mg/kg daily

AND

- Levofloxacin, oral, daily
  - 30 to 45kg: 750mg
  - ≥46kg: 1000mg

Duration: At least 6 months

Discuss these patients with infectious diseases specialist or pulmonology specialist.

HEPATOTOXICITY IN PATIENTS ON ART AND ANTI-TB TREATMENT

ADULTS

» Stop TB therapy, initiate background TB therapy and continue throughout rechallenge:

- Linezolid, oral 600 mg daily
- Levofloxacin, oral, 750–1000 mg daily or Moxifloxacin, oral, 400 mg daily
- Ethambutol, oral, 800–1200 mg daily

If ethambutol is unavailable replace with **either**:

- Terizidone (10-15mg/kg daily, max 750mg)

OR

- Amikacin (15mg/kg daily, IV/IM)
  - Avoid amikacin if eGFR < 60 mL/min and IM amikacin if INR > 1.5

OR

- Clofazimine (100mg daily)

» Stop cotrimoxazole prophylaxis.
» Stop ART *(See Adult Hospital Level STGs and EML, Chapter 10: HIV and AIDS, Section 10.1.1 Management of Selected Antiretroviral Adverse Drug Reactions, sub-section: Hepatotoxicity and Hepatitis in patients on ART and anti-TB therapy).*
» Repeat ALT and bilirubin in 2 days (inpatient) or 7 days (outpatient).
» When ALT is <100 IU/L and total bilirubin is less than twice the upper limit of normal, start TB medicine rechallenge as follows:

Day 1:	• Rifampicin, oral 600 mg daily. o If <60 kg: rifampicin, oral 450 mg daily.
Day 3:	» Check ALT.
Day 4–6:	**ADD** • Isoniazid, oral 300 mg daily **OR** • Switch to RH
Day 7	» Check ALT.
Day 8:	» Stop moxifloxacin/levofloxacin and linezolid (continue ethambutol). » Rechallenge pyrazinamide by switching to weight-based RHZE (*only in patients who have not yet completed the intensive phase*).
Day 10	» Check ALT. » Thereafter, monitor ALT twice weekly for the first 3 weeks, then every two weeks for a month, then monthly until 3 months. • Restart ART 2 weeks after completing rechallenge of TB therapy. o Monitor ALT every 2 weeks for 2 months after ART rechallenge.

Provinces should report any new incidents of rifampicin or INH resistance in patients treated with the interim regimen.

MYCOBACTERIOSIS – DISSEMINATED NON-TUBERCULOUS MYCOBACTERIA

Disseminated infection due to non-tuberculous mycobacteria (NTM), usually *Mycobacterium avium* complex (MAC).

- Confirm NTM species (culture and speciation).
- If ethambutol not available: **DO NOT** modify the regimen independently.
- Continue other active drugs if safe to do so.
- Urgently discuss/refer to an infectious diseases or pulmonology specialist.

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:
HEALTH PRODUCTS PROCUREMENT
DATE: 24 April 2026

PROF N NDJEKA
CHIEF DIRECTOR:
TB CONTROL & MANAGEMENT
DATE: 29/04/2026

Annexure: Levofloxacin Dosing Chart

Dosing guidance adapted from Western Cape Government and University of Cape Town Medicine Information Centre: Drug-resistant-TB treatment dosing table for children (< 46 kg and < 15 years).

	Levofloxacin
Formulations	250 mg tablet **OR** 500 mg tablet
Target dose	15 - 20 mg/kg/day
MDD	1.5 g
Practical advice	For a 25 mg/mL suspension: crush and disperse 1 x 250 mg tablet in 10 mL water*
Wt (kg)	Consult with a clinician experienced with DR-TB prescribing for children weighing < 5 kg.
3 - 4.9	2 mL daily (25mg/mL suspension)
5 – 9.9	5 mL (25mg/mL suspension) **OR** ½ x 250 mg tablet daily
10 – 15.9	1 x 250 mg tablet daily
16 – 23.9	1 ½ x 250 mg tablet daily
24 – 29.9	2 x 250 mg tablets daily **OR** 1 x 500 mg tablet daily
30 – 45.9	1 ½ x 500 mg tablet **OR** 3 x 250 mg tablets daily

**In general, for older children able to swallow tablets/capsules whole, avoid crushing and mixing tablets/capsules with water, as this may reduce palatability. Discard any unused portion of a non-commercial solution.*