



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)	<ul style="list-style-type: none"> <li>Continue RHZ, omit ethambutol</li> <li>Monitor carefully and report any new incidents of isoniazid and/or rifampicin resistance</li> </ul>
RH phase (children <25kg)	<ul style="list-style-type: none"> <li>No modification</li> </ul>
Non-tuberculous mycobacteria	<ul style="list-style-type: none"> <li>Discuss with a specialist</li> </ul>

*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	<b>Seek paediatrician guidance</b>	
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

## NOTICE: NON-AVAILABILITY OF ETHAMBUTOL 400MG TABLETS

For children  $\geq$  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](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  $\geq$  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](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:

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Day 1:	<ul style="list-style-type: none"> <li>• Rifampicin, oral 600 mg daily.</li> <li>○ If &lt;60 kg: rifampicin, oral 450 mg daily.</li> </ul>
Day 3:	» Check ALT.
Day 4–6:	<p><b>ADD</b></p> <ul style="list-style-type: none"> <li>• Isoniazid, oral 300 mg daily</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Switch to RH</li> </ul>
Day 7	» Check ALT.
Day 8:	<ul style="list-style-type: none"> <li>» Stop moxifloxacin/levofloxacin and linezolid (continue ethambutol).</li> <li>» Rechallenge pyrazinamide by switching to weight-based RHZE (<i>only in patients who have not yet completed the intensive phase</i>).</li> </ul>
Day 10	<ul style="list-style-type: none"> <li>» Check ALT.</li> <li>» Thereafter, monitor ALT twice weekly for the first 3 weeks, then every two weeks for a month, then monthly until 3 months.</li> <li>• Restart ART 2 weeks after completing rechallenge of TB therapy. <ul style="list-style-type: none"> <li>○ Monitor ALT every 2 weeks for 2 months after ART rechallenge.</li> </ul> </li> </ul>

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

**MYCOBACTERIOSIS – DISSEMINATED NON-TUBERCULOUS MYCOBACTERIA**

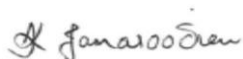
Disseminated infection due to non-tuberculous mycobacteria (NTM), usually *Mycobacterium avium* complex (MAC).

- 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).*

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