

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB367 trade name]* Ethambutol hydrochloride 50 mg dispersible tablets
Ethambutol hydrochloride

2. Statement of active substance

Each tablet contains 50 mg ethambutol hydrochloride.

3. List of excipients

4. Pharmaceutical form and contents

Dispersible tablets
10 x 10 tablets

5. Method and route of administration

Oral use.
Do not chew.
Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine out of the sight and reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

11. Name and address of the supplier

Micro Labs Limited
31, Race Course Road
Bengaluru, Karnataka, 560001
India

12. WHO Reference Number (Prequalification Programme)

TB367

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium strip pack

1. Name of the medicinal product

[TB367 trade name] Ethambutol hydrochloride 50 mg dispersible tablets
Ethambutol hydrochloride

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other