

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[TB411 trade name]* Ethambutol (as hydrochloride) 100 mg dispersible tablets
Ethambutol hydrochloride

2. Statement of active substance

Each dispersible tablet contains 100 mg ethambutol hydrochloride

3. List of excipients

Each dispersible tablet contains 20 mg of aspartame
See patient information leaflet for further information

4. Pharmaceutical form and contents

Dispersible tablets
10x10 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

Store below 30°C. Protect from excessive heat and moisture.

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

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

11. Name and address of the supplier

Lupin Limited
Kalpataru Inspire, 3rd Floor,
Off Western Express Highway,
Santacruz (East),
Mumbai 400055,
India.
Tel: 91-22-66402323

12. WHO Reference Number (Prequalification Programme)

TB411

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

Strip

1. Name of the medicinal product

[TB411 trade name] Ethambutol (as hydrochloride) 100 mg dispersible tablets

Ethambutol hydrochloride

2. Name of the supplier

Lupin Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other