

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for blister

1. Name of the medicinal product

[TB177 trade name]* Ethambutol hydrochloride 400mg tablets name
Ethambutol hydrochloride

2. Statement of active substance

Each tablet contains 400 mg ethambutol hydrochloride

3. List of excipients

Contains FD&C YELLOW #6 / lake of sunset yellow

4. Pharmaceutical form and contents

100 (10 x 10) film-coated tablets

672 (28 x 24) film-coated tablets

5. Method and route of administration

Oral use.

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. Store in a dry place.

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 Ltd.
Kalpataru Inspire,
3rd Floor, Off Western Express Highway
Santacruz (East)
400055 Mumbai
India
Tel : +91 22 66402370
Fax: +91 22 26528321

12. WHO Reference Number (Prequalification Programme)

TB177

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
PVC-PVDC/Alu

1. Name of the medicinal product

[TB177 trade name] Ethambutol hydrochloride 400mg tablets

Ethambutol hydrochloride

2. Name of the supplier

Lupin Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other