

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE pot

1. Name of the medicinal product

[TB008 trade name]* Ethambutol hydrochloride 400 mg tablets
Ethambutol hydrochloride

2. Statement of active substance

Each film-coated tablet contains 400 mg ethambutol hydrochloride

3. List of excipients

Contains sorbitol

4. Pharmaceutical form and contents

Film-coated tablet
1000 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

Store below 30°C. Protect from light.

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

Cadila Pharmaceuticals Limited
1389, Dholka – 382225
Ahmedabad, Gujarat
India

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
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12. WHO Reference Number (Prequalification Programme)

TB008

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB008 trade name][†] Ethambutol hydrochloride 400 mg tablets
Ethambutol hydrochloride

2. Statement of active substance

Each film-coated tablet contains 400 mg ethambutol hydrochloride

3. List of excipients

Contains sorbitol

4. Pharmaceutical form and contents

Film-coated tablet
10 x 10 tablets
24 x 28 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

Store below 30°C. Protect from light.

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

Cadila Pharmaceuticals Limited
1389, Dholka – 382225
Ahmedabad, Gujarat

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

India

12. WHO Reference Number (Prequalification Programme)

TB008

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

PVC/PVDC-Alu and PVC-Alu blisters

1. Name of the medicinal product

[TB008 trade name] Ethambutol hydrochloride 400 mg tablets
Ethambutol hydrochloride

2. Name of the supplier

Cadila Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other