

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE container

1. Name of the medicinal product

[TB134 trade name]*

Ethambutol (as hydrochloride) 400 mg film-coated tablets

2. Statement of active substance

Each film coated tablet contains 400 mg ethambutol hydrochloride

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets.

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 out of the reach and sight of children.

7. Other special warning(s), if necessary

None

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Store in the original container.

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

None

11. Name and address of the supplier

Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
Marol Church Road,

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

Andheri (East),
Mumbai- 400 059,
India

12. WHO Reference Number (Prequalification Programme)

TB134

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

Carton (Blister)

1. Name of the medicinal product

[TB134 trade name][†]

Ethambutol hydrochloride 400 mg film-coated tablets

2. Statement of active substance

Each film coated tablet contains 400 mg ethambutol hydrochloride.

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets.

24 x 28 tablets

9 x 10 tablets

10 x 10 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 out of the reach and sight of children.

7. Other special warning(s), if necessary

None

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C. Store in the original container.

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

None

11. Name and address of the supplier

Macleods Pharmaceuticals Ltd.

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

304, Atlanta Arcade,
Marol Church Road,
Andheri (East),
Mumbai- 400 059,
India

12. WHO Reference Number (Prequalification Programme)

TB134

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 ALUMINIUM SACHET OR
BLISTER PACK**

1. Name of the medicinal product

[TB134 trade name]

Ethambutol hydrochloride 400 mg film-coated tablets

2. Name of the supplier

Macleods Pharmaceuticals Ltd

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch><Lot>{number}

5. Other