

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (blister)

1. Name of the medicinal product

[TB334 trade name]* Ethambutol hydrochloride 100 mg dispersible tablets
Ethambutol hydrochloride

2. Statement of active substance

Each dispersible tablet contains 100 mg of ethambutol hydrochloride.

3. List of excipients

Each tablet contains aspartame and propylene glycol.
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

10 x 10 dispersible 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, protected from light. Avoid excursions over 30°C.
Store tablets in the blisters in the provided carton.

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.
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11. Name and address of the supplier

Macleods Pharmaceuticals Limited
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB334

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 (strip)

1. Name of the medicinal product

[TB334 trade name][†] Ethambutol hydrochloride 100 mg dispersible tablets
Ethambutol hydrochloride

2. Statement of active substance

Each dispersible tablet contains 100 mg of ethambutol hydrochloride.

3. List of excipients

Each tablet contains aspartame and propylene glycol.
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

10 x 6 dispersible tablets
8 x 10 dispersible 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, protected from light. Avoid excursions over 30°C.
Store tablets in the blisters in the provided carton.

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

Macleods Pharmaceuticals Limited
304, Atlanta Arcade,
Marol Church road,
Andheri (East),
Mumbai – 400 059, India

12. WHO Reference Number (Prequalification Programme)

TB334

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

1. Name of the medicinal product

[TB334 trade name] Ethambutol hydrochloride 100 mg dispersible tablets
Ethambutol hydrochloride

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other