

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB226 trade name]*

Ethambutol hydrochloride 100 mg tablets

2. Statement of active substance

Each tablet contains ethambutol hydrochloride 100 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

1 000 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

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

Keep out of reach and sight of children.

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

Atlanta Arcade, 3rd Floor, Church Road, near Leela Hotel,

Andheri-Kurla Road

Andheri (East)

400 059 Mumbai

India

12. WHO Reference Number (Prequalification Programme)

TB226

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

Outer carton

1. Name of the medicinal product

[TB226 trade name][†]

Ethambutol hydrochloride 100 mg tablets

2. Statement of active substance

Each tablet contains ethambutol hydrochloride 100 mg

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

7 x 10 tablets

10 x 10 tablets

24 x 28 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

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

Keep out of reach and sight of children.

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

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

Macleods Pharmaceuticals Limited

Atlanta Arcade, 3rd Floor, Church Road, near Leela Hotel,

Andheri-Kurla Road

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400 059 Mumbai

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12. WHO Reference Number (Prequalification Programme)

TB226

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

Blisters

1. Name of the medicinal product

[TB226 trade name][‡]

Ethambutol hydrochloride 100 mg tablets

2. Name of the supplier

Macleods Pharmaceuticals Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other

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