LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB406 trade name][*] Ethambutol hydrochloride 100 mg dispersible tablets
Ethambutol hydrochloride

2. Statement of active substance

Each dispersible tablet contains 100 mg ethambutol hydrochloride.

3. List of excipients

Each tablet contains 20 mg of aspartame

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Dispersible 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 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. Avoid excursion above 30°C.

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 Trasad Road,
Dholka - 382 225, District: Ahmedabad,
Gujarat, India

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

12. WHO Reference Number (Prequalification Programme)

TB406

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
Aluminium strip pack/Aluminium blister pack

1. Name of the medicinal product

[TB406 trade name] Ethambutol hydrochloride 100 mg dispersible 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