

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **Blister carton**

**1. Name of the medicinal product**

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

**2. Statement of active substance**

Each tablet contains 400 mg ethambutol hydrochloride.

**3. List of excipients**

**4. Pharmaceutical form and contents**

Film-coated tablets

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 out of the 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  
District: Ahmedabad  
Gujarat, 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.

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

## **15. Instructions on use**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

### **HDPE bottle**

**1. Name of the medicinal product**

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

**2. Statement of active substance**

Each 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 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  
District: Ahmedabad  
Gujarat, 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 blister**

**1. Name of the medicinal product**

[TB008 trade name] Ethambutol hydrochloride 400mg 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**