

## **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

### **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 out of the 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**

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\* 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**

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

Carton (strip)

### **1. Name of the medicinal product**

[TB334 trade name]

Ethambutol hydrochloride 100 mg dispersible tablets

### **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 out of the 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. 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**

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 STRIPS**

### **1. Name of the medicinal product**

[TB334 trade name]

Ethambutol hydrochloride 100 mg dispersible 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**