

## **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. Use within 30 days once opened.

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**

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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  
Atlanta Arcade, Marol Church Road,  
Andheri (East)  
Mumbai 400 059  
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]<sup>†</sup>

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.

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<sup>†</sup> 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, Marol Church Road,  
Andheri (East)  
Mumbai 400 059  
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**

## **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**