

## **LABELLING**

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

HDPE bottle

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

[TB133 trade name]\* Ethionamide 250 mg tablets

Ethionamide

### **2. Statement of active substance**

Each film-coated tablet contains 250 mg ethionamide

### **3. List of excipients**

### **4. Pharmaceutical form and contents**

Film-coated tablets

100 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. 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)

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

Mumbai– 400 059

India

**12. WHO Reference Number (Prequalification Programme)**

TB133

**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

**1. Name of the medicinal product**

[TB133 trade name]<sup>†</sup> Ethionamide 250 mg tablets

Ethionamide

**2. Statement of active substance**

Each film-coated tablet contains 250 mg ethionamide

**3. List of excipients**

**4. Pharmaceutical form and contents**

Film-coated tablets

10 x 10 tablets

9 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. 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

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Andheri (East)  
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**12. WHO Reference Number (Prequalification Programme)**

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**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 STRIP**

Aluminium/aluminium strip pack

**1. Name of the medicinal product**

[TB133 trade name] Ethionamide 250 mg tablets  
Ethionamide

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**