

## **LABELLING**

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

### **Bottle**

- 1. Name of the medicinal product**  
[TB199 trade name]\* Ethambutol hydrochloride/ Isoniazid/ Rifampicin 275mg/75mg/150mg Tablets
- 2. Statement of active substance**  
Each tablet contains ethambutol hydrochloride 275 mg, isoniazid 75 mg and rifampicin 150 mg
- 3. List of excipients**
- 4. Pharmaceutical form and contents**  
Film-coated tablets  
1 000 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**  
Store in a dry place, below 25°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**  
Lupin Limited  
Kalpataru Inspire, 3<sup>rd</sup> Floor  
Off Western Express Highway  
Santacruz (East), Mumbai 400055, India
- 12. WHO Reference Number (Prequalification Programme)**  
TB199
- 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**

---

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

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

### **Blister carton**

**1. Name of the medicinal product**

[TB199 trade name] Ethambutol hydrochloride/ Isoniazid/ Rifampicin 275mg/75mg/150mg  
Tablets

**2. Statement of active substance**

Each tablet contains ethambutol hydrochloride 275 mg, isoniazid 75 mg and rifampicin 150 mg

**3. List of excipients**

**4. Pharmaceutical form and contents**

Film-coated tablets

24 x 28 tablets

24 x 14 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**

*PVC/PVDC-aluminium and PVC/PE/PVDC-aluminium blister carton*

Store in a dry place, below 25°C. Protect from light.

*Alu-Alu blister carton*

Store at temperature not exceeding 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**

Lupin Limited

Kalpataru Inspire, 3<sup>rd</sup> Floor

Off Western Express Highway

Santacruz (East), Mumbai 400055, India

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

TB199

**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**

**Blister**

**1. Name of the medicinal product**

[TB199 trade name]

Ethambutol hydrochloride/ Isoniazid/ Rifampicin 275mg/75mg/150mg Tablets

**2. Name of the supplier**

Lupin Ltd

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**