

## **LABELING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE  
THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING  
outer carton**

**1. NAME OF THE MEDICINAL PRODUCT**

Ethambutol hydrochloride/Isoniazid 400mg/150mg tablets\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains 400 mg ethambutol hydrochloride, 150 mg isoniazid.

**3. LIST OF EXCIPIENTS**

**4. PHARMACEUTICAL FORM AND CONTENTS**

100 (10x10) film-coated tablets  
392 (14x28) film-coated tablets  
672 (24x28) film-coated tablets

**5. METHOD AND ROUTE OF ADMINISTRATION**

Oral use  
Read the package 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 and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

**8. EXPIRY DATE**

EXP {MM/YYYY}

\* Trade names are not prequalified by WHO. This is under local DRA responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 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**

Cadila Pharmaceuticals Limited  
1389, Dholka 387 810  
District : Ahmedabad  
Gujarat State  
India  
Phone: + 91 2714 221481-83  
Fax: + 91 2714 220315  
E-mail: mona.gogia@cadilapharma.co.in

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB009

**13. MANUFACTURER'S BATCH NUMBER**

Batch No.:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS  
PVC/PVDC/Alu**

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**2. NAME OF THE SUPPLIER**

Cadila Pharmaceuticals Ltd.

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

Batch No.:

**5. OTHER**