

## **LABELLING**

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

### **Bottle carton (HDPE bottles)**

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

[TB070 trade name]<sup>1</sup> Ethambutol hydrochloride/ isoniazid/ pyrazinamide/ rifampicin 275 mg/ 75 mg/  
400 mg/ 150 mg tablets

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

Each tablet contains 275 mg Ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and  
150 mg rifampicin tablets

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

See patient information leaflet for further information.

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

1000 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 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 25°C. Protect from light and excessive humidity.

#### **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

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Ethambutol hydrochloride/ isoniazid/  
pyrazinamide/ rifampicin 275mg/ 75mg/  
400mg/ 150mg tablets, (Lupin Ltd), TB070

WHOPAR Part 5

Updated: August 2023

3rd Floor, Off Western Express  
Highway  
Santacruz (East)  
Mumbai 400055  
India  
Tel: +91-22-66402323  
Fax: +91 -22-66408128

**12. WHO Reference Number (Prequalification Programme)**  
TB070

**13. Manufacturer's batch number**

<Batch> {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**

### **Blister (PVC/PVDC-Alu) /Carton Label**

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

[TB070 trade name]<sup>2</sup> Ethambutol hydrochloride/ isoniazid/ pyrazinamide/ rifampicin 275 mg/ 75 mg/  
400 mg/ 150 mg tablets

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

Each tablet contains 275 mg Ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and  
150 mg rifampicin tablets

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

See patient information leaflet for further information.

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

15 x 6 tablets

24 x 28 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 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 25°C. Protect from light and excessive humidity.

#### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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<sup>2</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**11. Name and address of the supplier**

Lupin Limited  
Kalpataru Inspire  
3rd Floor, Off Western Express  
Highway  
Santacruz (East)  
Mumbai 400055  
India  
Tel: +91-22-66402323  
Fax: +91 -22-66408128

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

TB070

**13. Manufacturer's batch number**

<Batch> { 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**

### **Blister (Alu-Alu) /Carton Label**

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

[TB070 trade name]<sup>3</sup> Ethambutol hydrochloride/ isoniazid/ pyrazinamide/ rifampicin 275 mg/ 75 mg/  
400 mg/ 150 mg tablets

#### **17. Statement of active substance**

Each tablet contains 275 mg Ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and  
150 mg rifampicin tablets

#### **18. List of excipients**

See patient information leaflet for further information.

#### **19. Pharmaceutical form and contents**

15 x 6 tablets

24 x 14 tablets

#### **20. Method and route of administration**

Oral use

Read the patient information leaflet before use.

#### **21. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep out of the sight and reach of children.

#### **22. Other special warning(s), if necessary**

#### **23. Expiry date**

EXP {MM/YYYY}

#### **24. Special storage conditions**

Do not store above 25°C. Protect from light and excessive humidity.

#### **25. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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<sup>3</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**26. Name and address of the supplier**

Lupin Limited  
Kalpataru Inspire  
3rd Floor, Off Western Express  
Highway  
Santacruz (East)  
Mumbai 400055  
India  
Tel: +91-22-66402323  
Fax: +91 -22-66408128

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

TB070

**28. Manufacturer's batch number**

<Batch> { number }

**29. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**30. Instructions on use**

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

### **Blister (PVC/PE/PVDC-Alu) /Carton Label**

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

[TB070 trade name]<sup>4</sup> Ethambutol hydrochloride/ isoniazid/ pyrazinamide/ rifampicin 275 mg/ 75 mg/  
400 mg/ 150 mg tablets

#### **32. Statement of active substance**

Each tablet contains 275 mg Ethambutol hydrochloride, 75 mg isoniazid, 400 mg pyrazinamide and  
150 mg rifampicin tablets

#### **33. List of excipients**

See patient information leaflet for further information.

#### **34. Pharmaceutical form and contents**

24 x 28 tablets

#### **35. Method and route of administration**

Oral use

Read the patient information leaflet before use.

#### **36. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep out of the sight and reach of children.

#### **37. Other special warning(s), if necessary**

#### **38. Expiry date**

EXP {MM/YYYY}

#### **39. Special storage conditions**

Do not store above 25°C. Protect from light and excessive humidity.

#### **40. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

#### **41. Name and address of the supplier**

Lupin Limited

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Ethambutol hydrochloride/ isoniazid/  
pyrazinamide/ rifampicin 275mg/ 75mg/  
400mg/ 150mg tablets, (Lupin Ltd), TB070

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**42. WHO Reference Number (Prequalification Programme)**  
TB070

**43. Manufacturer's batch number**

<Batch> {number}

**44. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**45. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

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

[TB070 trade name]<sup>5</sup> Ethambutol hydrochloride/ isoniazid/ pyrazinamide/ rifampicin 275 mg/ 75 mg/  
400 mg/ 150 mg tablets

### **2. Name of the supplier**

Lupin Limited

### **3. Expiry date**

EXP {MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> {number}

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<sup>5</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.