

## **LABELLING**

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

HDPE container

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

[TB361 trade name]\*

clofazimine 50 mg tablets

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

Each film-coated tablet contains 50 mg clofazimine.

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

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

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

Film-coated tablet

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 out of the reach and sight 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. Avoid excursions above 30°C.

### **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  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
INDIA

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

TB361

**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**

Blister pack

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

[TB361 trade name]

clofazimine 50 mg tablets

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

Each film-coated tablet contains 50 mg clofazimine.

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

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

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

Film-coated tablet

10x10 tablets

10x28 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 reach and sight of children.

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

### **23. Expiry date**

EXP {MM/YYYY}

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

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

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

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

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
INDIA

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

TB361

**28. Manufacturer's batch number**

<Batch> <Lot> {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**

Strip pack

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

[TB361 trade name]

clofazimine 50 mg tablets

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

Each film-coated tablet contains 50 mg clofazimine.

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

Contains castor oil polyoxyl hydrogenated and betadex.

See the patient information leaflet for further information.

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

Film-coated tablet

10x10 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 reach and sight of children.

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

### **38. Expiry date**

EXP {MM/YYYY}

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

Do not store above 30°C. Protect from light. Avoid excursions above 30°C.

### **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**

Macleods Pharmaceuticals Limited

304, Atlanta Arcade  
Marol Church road  
Andheri (East)  
Mumbai – 400 059  
INDIA

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

TB361

**43. Manufacturer's batch number**

<Batch> <Lot> {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**  
PVC/PVDC-aluminium blister and polyethene film strip

**1. Name of the medicinal product**

[TB361 trade name]

clofazimine 50 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**