

## **LABELLING**

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

### **Bottle**

- 1. Name of the medicinal product**  
[TB302 trade name]\* Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets
- 2. Statement of active substance**  
Each tablet contains 50 mg isoniazid and 75 mg rifampicin.
- 3. List of excipients**  
Contains aspartame  
See patient information leaflet for further information.
- 4. Pharmaceutical form and contents**  
Dispersible 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}  
Date opened {DD/MM/YYYY}
- 9. Special storage conditions**  
Do not store above 25°C. Store in dry place. Protect from light.  
Once opened, use within 120 days.
- 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)  
Mumbai - 400 059  
India
- 12. WHO Reference Number (Prequalification Programme)**  
TB302
- 13. Manufacturer's batch number**  
<Batch> <Lot> {number}

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

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

Medicinal product subject to medical prescription.

**15. Instructions on use**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**  
**Strip pack carton**

- 1. Name of the medicinal product**  
[TB302 trade name] Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets
- 2. Statement of active substance**  
Each tablet contains 50 mg isoniazid and 75 mg rifampicin.
- 3. List of excipients**  
Contains aspartame  
See patient information leaflet for further information.
- 4. Pharmaceutical form and contents**  
Dispersible tablets  
10 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 25°C, store in dry place, 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)  
Mumbai - 400 059  
India
- 12. WHO Reference Number (Prequalification Programme)**  
TB302
- 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**

Alu/Alu strip

**1. Name of the medicinal product**

[TB302 trade name] Isoniazid/Rifampicin 50mg/75mg Dispersible Tablets

**2. Name of the supplier**

Macleods Pharmaceuticals Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**

## **MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{Nature/type}

### **1. Name of the medicinal product and route(s) of administration**

[<PQ number> trade name] {name} {strength} {pharmaceutical form}

{Active substance(s)}

{Route(s) of administration}

### **2. Method of administration**

### **3. Expiry date**

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

<Batch> <Lot> {number}

### **5. Contents by weight, by volume, or by unit**

### **6. Other**