

## **LABELLING**

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

Carton (Blister and strip)

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

[TB332 trade name]\* Rifampicin 300 mg Capsules  
Rifampicin

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

Each capsule contains 300 mg rifampicin

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

Contains carmoisine (azorubine), sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sunset yellow (FD&C yellow #6) and ponceau 4R (cochineal red A)  
See the patient information leaflet for further information.

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

10 x 10 capsules

### **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 at a temperature not exceeding 25°C, in a dry place, protected from light.

Store capsules in blisters in the provided carton.

### **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)**

TB332

**13. Manufacturer's batch number**

<Batch> {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 (Strips) and PVC-ALU (Blister cards)

**1. Name of the medicinal product**

[TB332 trade name] Rifampicin 300 mg Capsules  
Rifampicin

**2. Name of the supplier**

Macleods Pharmaceuticals Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**

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

HDPE container

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

[TB332 trade name] Rifampicin 300 mg Capsules

Rifampicin

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

Each capsule contains 300 mg rifampicin

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

Contains carmoisine (azorubine), sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sunset yellow (FD&C yellow #6) and ponceau 4R (cochineal red A).

See the patient information leaflet for further information

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

100 capsules

### **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**

Store at a temperature not exceeding 25°C, in a dry place, protected from light.

Store capsules in blisters in the provided carton.

### **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)**

TB332

**13. Manufacturer's batch number**

<Batch> {number}

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

Medicinal product subject to medical prescription

**15. Instructions on use**