

## **LABELLING**

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

HDPE Bottle

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

[TB365 trade name]\* Linezolid 600 mg film-coated tablets  
Linezolid

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

Each film-coated tablet contains 600 mg linezolid.

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

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

Film-coated tablets

30 tablets

100 tablets

200 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 30°C. Store in the original container. Do not remove the silica gel/activated carbon canister from the bottle.

### **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**

Mylan Laboratories Ltd  
Plot No. 564/A/22

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

Road No. 92 Jubilee Hills  
Hyderabad,  
Telangana, 500096  
India  
Email: Imtiyaz.basade@mylan.in

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

TB365

**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**