

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**  
**HDPE Bottle Label**

**1. Name of the medicinal product**

[TB351 trade name]<sup>1</sup> Linezolid 600 mg tablets

Linezolid

**2. Statement of active substance**

Each film-coated tablet contains 600 mg of linezolid

**3. List of excipients**

Contains lactose. See patient information leaflet for further information

**4. Pharmaceutical form and contents**

10 film-coated tablets

20 film-coated tablets

30 film-coated tablets

100 film-coated 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 30°C. Store in the original bottle.

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

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

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

Celltrion Inc.  
23 Academy -ro, Yeonsu-gu  
Incheon, 22014  
Republic of Korea

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

TB351

**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**

### **Carton label for blister pack**

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

[TB351 trade name]<sup>2</sup> Linezolid 600 mg tablets

Linezolid

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

Each film-coated tablet contains 600 mg of linezolid

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

Contains lactose. See patient information leaflet for further information

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

10 film-coated tablets

20 (10 x 2) film-coated tablets

30 (10 x 3) film-coated tablets

60 (10 x 6) film-coated tablets

100 (10 x10) film-coated 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 30°C. Store the tablets in the 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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<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**

Celltrion Inc.  
23 Academy-ro, Yeonsu-gu  
Incheon, 22014  
Republic of Korea

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

TB351

**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 STRIPS**

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

[TB351 trade name]<sup>3</sup> Linezolid 600 mg tablets

Linezolid

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

Celltrion Inc.

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> {number}

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