

## **LABELLING**

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

### **Carton for HDPE and HDPE Bottle label**

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

[TB299 trade name]\*

Linezolid 600 mg film-coated tablets

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

Each film-coated tablet contains linezolid 600 mg

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

Contains lactose

See patient information leaflet for further information.

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

Film-coated tablets

20 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**

Not applicable

#### **8. Expiry date**

EXP {MM/YYYY}

#### **9. Special storage conditions**

Store in the original bottle. Do not store above 30°C. Protect from moisture.

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

NA

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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**

Hetero Labs Limited  
7-2-A2, Hetero Corporate  
Industrial Estates  
Sanath Nagar Hyderabad – 500018  
Telangana  
India

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

TB299

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. General classification for supply**

To be decided by the national medicines regulatory authority in accordance with national legislation.

**15. Instructions on use**

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

### **Carton label for Blister pack**

**1. Name of the medicinal product**

[TB299 trade name]

Linezolid 600 mg film-coated tablets

**2. Statement of active substance**

Each film coated tablet contains Linezolid 600 mg

**3. List of excipients**

Contains lactose

See patient information leaflet for further information

**4. Pharmaceutical form and contents**

Film-coated 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**

Not applicable

**8. Expiry date**

EXP {MM/YYYY}

**9. Special storage conditions**

Do not store above 30°C. Protect from moisture. Store in the original container.

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

NA

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

Hetero Labs Limited

7-2-A2,Hetero Corporate

Industrial Estates  
Sanath Nagar Hyderabad – 500018  
Telangana  
India

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

TB299

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. General classification for supply**

To be decided by the national medicines regulatory authority in accordance with national legislation.

**15. Instructions on use**

## MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

### Alu-Alu Blister

**1. Name of the medicinal product**

[TB299 trade name]

Linezolid 600 mg film-coated tablets

**2. Name of the supplier**

Hetero Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**