

## **LABELLING**

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

### **Carton label**

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

[TB391 trade name]<sup>1</sup> Linezolid 150 mg dispersible tablets  
Linezolid

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

Each tablet contains 150 mg of linezolid

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

Each dispersible tablet contains 30 mg of aspartame and 32.46 mg (1.4 mmol) of sodium.  
See patient information leaflet for further information.

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

8 x 10 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**

Store below 30°C in a dry place. Avoid excursions over 30°C.

#### **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

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

Linezolid 150 mg dispersible tablets  
(Macleods Pharmaceuticals Limited),  
TB391

WHOPAR Part 5

May 2023

Plot No.50 to 54A  
SEZ, Phase II  
Pithampur,Dist.: Dhar  
Madhya Pradesh, 454774  
India

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

TB391

**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 STRIPS

### 1. Name of the medicinal product

[TB391 trade name]<sup>2</sup> Linezolid 150 mg dispersible tablets  
Linezolid

### 2. Name of the supplier

Macleods Pharmaceuticals Limited

### 3. Expiry date

EXP {MM/YYYY}

### 4. Manufacturer's batch number

<Batch> {number}

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<sup>2</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.