

## **LABELLING**

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

### **Carton**

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

[TB326 trade name]\* Levofloxacin (as hemihydrate) 100 mg Dispersible Tablets  
Levofloxacin (as hemihydrate)

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

Each dispersible tablet contains levofloxacin (as hemihydrate) equivalent to levofloxacin 100 mg

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

Each tablet contains 20 mg of aspartame and 5.8 mg (0.2 mmol) sodium  
See patient information leaflet for further information.

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

Tablets  
10 x 10 dispersible 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 dry place protected from light.  
Store tablets in the blisters or strips 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

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

304, Atlanta Arcade,  
Marol Church road,  
Andheri (East),  
Mumbai – 400 059, India

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

TB326

**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**

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

ALU/ALU Blister or Strip

**1. Name of the medicinal product**

[TB326 trade name] Levofloxacin (as hemihydrate) 100 mg Dispersible Tablets

Levofloxacin (as hemihydrate)

**2. Name of the supplier**

Macleods Pharmaceuticals Ltd

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**