

## **LABELLING**

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

Carton

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

[TB378 trade name]\*

Levofloxacin (as hemihydrate) 500mg tablets

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

Each tablet contains 500 mg of levofloxacin (as hemihydrate).

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

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

Film-coated tablet

4 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. Preserve in tight containers.

### **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**

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd  
333 Jiangnan Road  
Hengdian, Dongyang  
Zhejiang province

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

P.R. China

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

TB378

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. General classification for supply**

Medicinal product subject to medical prescription

**15. Instructions on use**

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

Blister

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

[TB378 trade name]

Levofloxacin (as hemihydrate) 500mg tablets

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

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> <Lot>{number}

### **5. Other**