

## **LABELLING**

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

Carton

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

[TB319 trade name]\*

Amikacin (as sulfate) 500 mg/2 mL solution for injection

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

Each ampoule contains 500 mg amikacin in 2 mL of solution

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

Each ampoule contains sodium metabisulfite.

See the patient information leaflet for further information.

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

Solution for injection

10 ampoules

### **5. Method and route of administration**

For intramuscular or intravenous 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. Avoid excursions above 30°C.

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

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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**

Qilu Pharmaceutical Co., Ltd.  
No. 23999 Gong Ye Bei Road  
Jinan, Shandong Province,  
250100  
P. R. China

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

TB319

**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 SMALL IMMEDIATE PACKAGING UNITS**

Ampoule

### **1. Name of the medicinal product and route(s) of administration**

[TB319 trade name]

Amikacin (as sulfate) 500 mg/2 mL solution for injection

### **2. Method of administration**

Intramuscular or intravenous injection

### **3. Expiry date**

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

<Batch> <Lot> {number}

### **5. Contents by weight, by volume, or by unit**

Amikacin 500 mg/2 mL

### **6. Other**