

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

**1. NAME OF THE MEDICINAL PRODUCT**

[TB328 trade name]<sup>1</sup>

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each ampoule contains 1000 mg Kanamycin (as sulfate)

**3. LIST OF EXCIPIENTS**

Contains sodium bisulphite and sodium

Read the patient information leaflet before use

**4. PHARMACEUTICAL FORM AND CONTENTS**

Solution for Injection

1 x 10 ampoules

**5. METHOD AND ROUTE OF ADMINISTRATION**

For intramuscular or intravenous use after reconstitution.

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 out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

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

**8. EXPIRY DATE**

EXP {MM/YYYY}

**9. SPECIAL STORAGE CONDITIONS**

Store below 30°C. Avoid freezing.

**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**

Livzon (Group) Pharmaceutical Factory  
No.38, Chuangye Road North,  
Jinwan District, Zhuhai,  
Guangdong, 519045, P. R. China

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

TB328

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS  
(Ampoule Label)**

**1. NAME OF THE MEDICINAL PRODUCT**

[TB328 trade name]

**2. NAME OF THE SUPPLIER**

Livzon (Group) Pharmaceutical Factory

**3. EXPIRY DATE**

EXP {MM/YYYY}

**4. BATCH NUMBER**

<Batch> <Lot> <BN> {number}