LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING Carton

1. NAME OF THE MEDICINAL PRODUCT

[TB327 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each ampoule contains 500 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

¹Trade 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)

TB327

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

[TB327 trade name]

2. NAME OF THE SUPPLIER

Livzon (Group) Pharmaceutical Factory

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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