

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

[TB318 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each vial contains 1000 kanamycin (as monosulfate)

3. LIST OF EXCIPIENTS

Sodium bisulfite, sodium citrate, sulfuric acid, water for injection

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

5 ampoules per carton.

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 sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

¹Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Protect from light.

Do not freeze.

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

Shanghai Harvest Pharmaceutical Co., Ltd
No. 805 Jinhua Road, Pudong,
Shanghai, 201 206,
P.R. China

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

TB318

13. MANUFACTURER'S BATCH NUMBER

Batch No. {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS
VIAL LABEL**

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

[TB318 trade name]

2. METHOD OF ADMINISTRATION

For intramuscular or intravenous use after reconstitution

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

BN {number}

5. CONTENTS BY WEIGHT, BY VOLUME, OR BY UNIT

Kanamycin (as monosulfate) 1000 mg

6. OTHER

Shanghai Harvest Pharmaceutical Co., Ltd