WHO-PQ RECOMMENDED
PATIENT INFORMATION LEAFLET

This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised).
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

Information for the patient

[TB318 trade name] [1]
kanamycin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider.This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB318 trade name] is and what it is used for

[TB318 trade name] contains the active ingredient kanamycin.

Kanamycin is an antibiotic which is used to treat tuberculosis (TB) caused by kanamycin-sensitive strains of *Mycobacterium tuberculosis* together with other medicines.

Kanamycin is only indicated as a second-line antimycobacterial drug when first-line drugs cannot be used because of resistance or intolerance.

2. What you need to know before you are given [TB318 trade name]

Do not take [TB318 trade name] if:

- you are allergic (hypersensitive) to kanamycin. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- you are pregnant

Take special care with [TB318 trade name] if:

- you have kidney problems
- you have hearing problems. Your health care provider may want to test your hearing and balance before you have [TB318 trade name]
- you have a history of allergies, especially to a class of antibiotics known as aminoglycosides

If any of the above applies to you, tell your health care provider.

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

Taking other medicines with [TB318 trade name]

Tell your health care provider if you are taking or have taken any medicines, including medicines obtained without a prescription. In particular, talk to your health care provider if you are taking any of the following medicines:

- streptomycin, amikacin,viomycin (other treatments for tuberculosis [TB])
- other aminoglycoside antibiotics, polymyxin, colistin, vancomycin, cephalosporins, penicillins, amphotericin B, ciclosporin, cisplatin, and loop diuretics (e.g. furosemide, etacrynic acid, mannitol)
- anaesthetics or muscle-relaxing drugs
- Botulinum Toxin
- anticoagulants
- bisphosphonates (drugs used to treat loss of bone mass)
- neostigmine or pyridostigmine (used for the treatment of myasthenia gravis).

It may still be alright for you to be given [TB318 trade name] and your health care provider will be able to decide what is suitable for you.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, planning to become pregnant or breast-feeding you should not take [TB318 trade name].

[TB318 trade name] can be used with caution while breast-feeding.

Ask your health care provider for advice before taking any medicine.

Driving and using machines

In large doses, kanamycin may cause muscle weakness. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert. Remember that if you are unwell your ability to drive or operate machinery may be affected.

[TB318 trade name] contains sodium

[TB318 trade name] contains l.08 mmol sodium (24.64 mg) per 4 mL, equivalent to 1.23% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How [TB318 trade name] is given

Dose

You will be given other TB antibiotic medicines while you are having [TB318 trade name].

[TB318 trade name] may be administered intramuscularly or intravenously. It will usually be given by a health care provider.

Adults

The usual dose is 15 mg/kg every day, 5 or 7 times a week, up to a maximum of 1 g daily. Your health care provider may adjust this dose according to your circumstances (e.g. because you are very overweight).

If you are older than 59 years or if you have kidney problems your health care provider may reduce your dose.

Children

The dose of kanamycin for a child is calculated according to the child's body weight. The recommended dose in children is
15–30 mg/kg every day, 5–7 times a week, up to a maximum of 1 g daily.

Your health care provider will tell you how long you or your child will be given [TB318 trade name].

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, kanamycin can cause side effects, but not everybody gets them. Tell your healthcare provider about any change in your health.

Very serious side effects

All medicines can cause allergic reactions but serious allergic reactions are very rare.

Tell your health care provider straightaway if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

- kidney or liver problems
- the amount of potassium, calcium and magnesium in your blood may decrease (symptoms are muscle weakness, muscle cramps, feeling thirsty all the time, drinking all the time, urinating frequently, vomiting and, possibly, having a fit)
- hearing or balance may get worse and you may hear noises in your ears or feel dizzy
- rash (without other symptoms)
- itching
- injection-site pain, bleeding or development of lumps in the skin where injected
- fever
- concurrent use of the Botulinum Toxin and aminoglycoside antibiotics may increase the risk of toxicity due to enhanced neuromuscular block.
- neuromuscular blockade (inhibition of a muscular contraction that is activated by your nervous system) and inability to breathe
- weakness in your muscles

If any side effects get serious or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If you get any side effects,talk to your health care provider.This includes unwanted effects not listed in this leaflet.If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [TB318 trade name]

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

Keep this medicine out of the sight and reach of children.

This medicine must not be used after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [TB318 trade name] contains

The active substance is kanamycin (as monosulfate) 1000 mg
The other ingredients of [TB318 trade name] are sodium bisulfite, sodium citrate, sulfuric acid and water for injection

What [TB318 trade name] looks like and contents of the pack

[TB318 trade name] is a colourless to slightly yellow or yellowish-green clear liquid contained in a 4 mL clear colourless type I mid-content borosilicate glass ampoule.

Each carton contains 5 ampoules.

Supplier and Manufacturer

Shanghai Harvest Pharmaceutical Co., Ltd
No. 805 Jinhu Road, Pudong,
Shanghai, 201 206, P.R. China
Tel: + 86 21 58548282
E-mail: harvest5@shharvest.com, harvest1@shharvest.com

For any information about this medicine, contact the supplier.

This leaflet was last revised in April 2020

Detailed information on this medicine is available on the World Health Organization (WHO) web site: https://extranet.who.int/prequal/.

<---------->

<The following information is intended for health care provider only:>

This information is intended for health care providers only:

INFORMATION FOR HEALTH CARE PROVIDERS

[TB318 trade name]

Please refer to the Summary of Product Characteristics for full prescribing information.

Posology and method of administration

Dose:

Adults
The usual dose is 15 mg/kg once daily on 5–7 days each week (usually up to a maximum of 1 g; a higher dose can be given to a large, muscular person but with monitoring of kanamycin concentration—see section 4.4 and 5.2 for serum concentrations).

Adults aged over 59 years
10 mg/kg (maximum 750 mg) once daily on 5–7 days each week, or 2–3 times each week (at roughly equal intervals throughout the week) after the initial treatment period.

Alternatively, 15 mg/kg once daily on 3 days each week, administered at roughly equal intervals throughout the week.

Renal Impairment
In patients with severe renal impairment (CL_{CR} < 30 ml/min or on dialysis), the dose should be adjusted to

12–15 mg/kg once daily, 2–3 times each week at roughly equal intervals throughout the week (see sections 4.4 and 5.2). In patients on haemodialysis, the dose should be given after the dialysis on the day of haemodialysis.

Children

There is limited reported experience on the use of second-line drugs, including kanamycin, for extended periods in children. Kanamycin should not be used in children with clinically-diagnosed disease associated with less severe clinical or radiological manifestations (see sections 4.4 and 5.1).

The usual dose is 15–30 mg/kg (maximum 1 g) once daily on 5–7 days each week.

Reconstitution of the kanamycin solution

1. Using a syringe, withdraw 3 ml of 0.9 % Sodium Chloride Injection or D5W for Injection
2. Inject the 0.9 % Sodium Chloride Injection or D5W for Injection into the vial containing the kanamycin sulfate powder for solution for injection.
3. Shake the vial for 2-3 minutes to mix well until the powder is completely dissolved and the solution is clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
4. The reconstituted kanamycin solution should always be used immediately.
   [TB318 trade name] are single-use vials. Discard unused portions.

Dilution for intravenous (IV) infusion and administration

1. Using a syringe, withdraw the required volume (see dilution table) from the vial containing the reconstituted [TB318 trade name] and introduce into 100 ml of 0.9% Sodium Chloride infusion bag. Shake to mix well, ensuring that the resulting solution is still clear. If the solution appears cloudy or a precipitate is present, it should be discarded.
2. Then intravenously infuse, over 60 minutes.
3. Reconstituted solutions diluted further with 100 ml 0.9% Sodium Chloride Injection should be used within 6 hours at 30°C±2°C.

   Note that the diluted [TB318 trade name] should be administered as an intravenous drip.

Administration by intramuscular (IM) injection

1. Withdraw the required volume of reconstituted [TB318 trade name] from the vial with a syringe and then inject intramuscularly; the anterior thigh is usually the preferred site for injection.
2. Reconstituted [TB318 trade name] should be given by deep intramuscular injection into a large muscle mass, since superficial injection may be associated with increased pain and the development of sterile abscesses.

For administration of a 1000 mg dose, the entire contents of the vial should be given. For doses lower than 1000 mg, the following dilution table may be used.

DILUTION TABLE

Diluent Added to 1000 mg, 10 ml Vial	Volume of Kanamycin Sulfate Solution	Concentration (Approx)
3 ml	3.8 ml	263.2 mg/ml
4 ml	4.9 ml	204.1 mg/ml

Approximated concentration takes into account the retention volume.

Reconstituted and further diluted solutions that show discoloration, haziness, visible particulate matter or precipitation should not be used

After reconstitution, all solutions of [TB318 trade name] should be used within 1 hour.