

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.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB319 trade name][†]
Amikacin (sulfate)

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 are concerned about 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 [TB319 trade name] is and what it is used for
2. What you need to know before you take [TB319 trade name]
3. How to take [TB319 trade name]
4. Possible side effects
5. How to store [TB319 trade name]
6. Contents of the pack and other information

1. What [TB319 trade name] is and what it is used for

[TB319 trade name] is an antibiotic that contains the active substance amikacin. It belongs to a group of antibiotics called aminoglycosides.

[TB319 trade name] can be used together with other medicines to treat multi-drug resistant tuberculosis (TB) caused by *Mycobacterium tuberculosis*. It is only used when more usual TB medicines cannot be used or no longer work.

2. What you need to know before you take [TB319 trade name]

Do not take [TB319 trade name] if you are:

- allergic (hypersensitive) to amikacin or any other ingredients of this medicine (see section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- allergic (hypersensitive) to other aminoglycosides

Take special care with [TB319 trade name] if you:

- have kidney problems
- have hearing problems, balance problems or feel dizzy. Your health care provider may want to test your hearing and balance before you have amikacin injections
- have a history of allergies, especially to other antibiotics related to amikacin
- have asthma
- have a neuromuscular disorder (such as Parkinson's disease or myasthenia gravis) or problems with muscle weakness
- are allergic to sulfites

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

- have recently been treated with another aminoglycoside antibiotic

If any of the above applies to you, tell your health care provider. Your health care provider will need to check your hearing and balance, and test if your kidneys are functioning well before and during your treatment or may decide that another treatment is better for you.

It is important to remain well hydrated during treatment; make sure that you drink enough each day.

Taking other medicines with [TB319 trade name]

You should tell your health care provider if you are taking or have taken any medicines, including medicines obtained without a prescription before you are given amikacin injections.

Some medicines can affect the action of other medicines or cause side effects if taken together with amikacin. It is especially important that you tell your doctor if you are taking:

- other antibiotics used for the treatment of tuberculosis (TB) that can affect your kidneys, hearing or balance: e.g. kanamycin, streptomycin
- other medicines that can affect your kidneys, hearing or balance such as other aminoglycoside antibiotics (e.g. gentamicin), amphotericin B, ciclosporin, cisplatin, methoxyflurane, polymyxin B, and colistin
- diuretics (water tablets) such as furosemide and ethacrynic acid
- anaesthetics or muscle-relaxing drugs such as ether, halothane, d-tubocurarine, succinylcholine decamethonium, atracurium, rocuronium, vecuronium
- botulinum toxin
- indomethacin (an anti-inflammatory medicine)
- other antibiotics called beta-lactamases such as penicillins or cephalosporins
- bisphosphonates (medicines used to treat loss of bone mass)
- vitamin B1 (thiamine)
- neostigmine or pyridostigmine (used to treat myasthenia gravis, a disease that causes muscle weakness)

Your health care provider may still decide to give you [TB319 trade name], but will need to check your general health, hearing and balance, and test if your kidneys are functioning well before and during your treatment. In other cases, your health care provider may decide that another treatment is better for you.

Pregnancy

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

[TB319 trade name] should not be taken if you are pregnant unless clearly indicated by your health care provider.

Breastfeeding

If you are breastfeeding, tell your health care provider before taking [TB319 trade name]. Small amounts of [TB319 trade name] have been shown to pass from the nursing mother's blood into the breast milk, but it is assumed that poor gastrointestinal absorption of [TB319 trade name] make it unlikely that neonatal toxicity would appear from milk exposure.

[TB319 trade name] can be used under caution during breastfeeding.

Driving and using machines

Amikacin may make you feel dizzy or experience problems with your balance. 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.

[TB319 trade name] contains sodium metabisulfite

Each ampoule contains 13.2 mg of sodium metabisulfite, a sulfite that may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (excessive contraction of the airway muscles causing difficult breathing).

3. How to take [TB319 trade name]

You will be given other TB medicines while you are given [TB319 trade name].

Amikacin is usually given by injection into a large muscle (deep intramuscular injection). It will usually be given to you by a health care provider. In certain circumstances it may need to be given into your vein.

Recommended dose

The usual dose is 15-20 mg/kg every day, 6 or 7 times a week. Your health care provider may adjust this dose according to your circumstances.

If you have kidney problems your health care provider may reduce your dose and give you this medicine less frequently.

Your health care provider will tell you for how long you will be given [TB319 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, [TB319 trade name] can cause side effects, but not everybody gets them. Tell your health care provider about any change in your health.

Very serious side effects

All medicines can cause allergic reactions but serious allergic reactions are very rare. If you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), contact your health care provider or your nearest hospital casualty department at once.

Common side effects (may affect between 1 in 100 and 1 in 10 people)

- dizziness
- hearing loss, ringing in the ears (tinnitus) and a spinning sensation
- kidney problems including a reduction of the amount of urine

Uncommon side effects (may affect between 1 in 100 and 1 in 1,000 people)

- infections with resistant bacteria or yeast
- feeling or being sick
- rash

Rare side effects (may affect between 1 in 1,000 and 1 in 10,000 people)

- fever
- changes in the number of different types of blood cells (a blood test will detect these). You may notice that you bruise easily (caused by low platelets) or you cannot fight off infections
- increases in enzymes in the blood which measure liver function
- low levels of magnesium in your blood
- sensations like numbness, tingling, pins and needles (paresthesia), tremor, problems with balance, headache
- decreased blood pressure
- itching, itchy rash
- joint pain
- muscle twitching
- increased heart rate
- inflammation of the heart muscle (myocarditis)

The following side effects have also been reported, but it is unknown how often they may occur:

- paralysis

- deafness
- interruption of breathing (apnoea), difficulty breathing
- severe kidney failure
- blood in the urine (haematuria)
- increase in serum creatinine
- release of albumin protein in the urine
- increase in nitrogen-containing protein products in the blood (azotaemia)

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 improve understanding about the safety of this medicine.

5. How to store [TB319 trade name]

Keep out of the sight and reach of children.

Store below 30°C. Avoid excursions above 30°C.

After reconstitution: following dilution with the infusion solutions, chemical and physical in-use stability has been demonstrated for 24 hours at 25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use [TB319 trade name] after the expiry date stated on the ampoule or carton after EXP. The expiry date refers to the last day of the month.

Medicines should not be disposed of in wastewater or household waste. Ask your health care provider how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What [TB319 trade name] contains

- Each ampoule contains 500 mg of the active substance amikacin.
- The other ingredients of [TB319 trade name] are: sodium metabisulfite, sodium citrate dihydrate, sulfuric acid (for pH adjustment), water for injection.

What [TB319 trade name] looks like and contents of the pack

A clear, colourless to slightly yellow liquid in 2 ml colourless type I glass ampoules.

10 ampoules are provided in a carton box.

Supplier and Manufacturer

Supplier

Qilu Pharmaceutical Co., Ltd.
No. 23999 Gong Ye Bei Road
Jinan, Shandong Province, 250100
P. R. China
Tel: 0086-531-83126268
e-mail: guilin.han@qilu-pharma.com

Manufacturer

Qilu Pharmaceutical Co., Ltd.
No. 317, Xinluo Road
High-Tech Zone
Jinan, Shandong
P.R. China
Tel: 0086-531-83126268
e-mail: guilin.han@qilu-pharma.com

For any information about this medicine, contact the supplier.

This leaflet was prepared in November 2021

Section 6 was updated in February 2024.

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>