

Amikacin sulphate Injection USP 100mg/2ml TajPharma
Amikacin sulphate Injection USP 250mg/2ml TajPharma
Amikacin sulphate Injection USP 500mg/ml TajPharma
Amikacin sulphate Injection USP 1g/4ml TajPharma

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

In this leaflet:

1. What Amikacin Injection is and what it is used for
2. Before you use Amikacin Injection
3. How to use Amikacin Injection
4. Possible side effects
5. How to store Amikacin Injection
6. Further information

1. What amikacin injection is and what it is used for

Amikacin Injection is one of a group of antibiotic medicines called 'aminoglycosides'.

Amikacin Injection is used in the treatment of serious infections caused by bacteria sensitive to amikacin.

2. Before you use amikacin injection

Do not use Amikacin Injection

If you have any further questions, ask your doctor or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

if you have shown signs of hypersensitivity (severe allergy) to amikacin, or any of the other ingredients listed in section 6, in the past if you suffer from a disorder called myasthenia gravis (severe weakness of certain muscles of the body)

Tell your doctor if any of the above applies to you before this medicine is used.

Take special care with Amikacin Injection

if you have kidney problems

if you have hearing difficulties or tinnitus (ringing or buzzing in the ears)

if you have shown signs of allergy to any of the antibiotics related to amikacin (aminoglycosides) in the past

If you have a known allergy to sulphites

Amikacin should be used with caution in premature and neonatal infants.

Tell your doctor if any of the above applies to you before this medicine is used.

Taking/using other medicines

Special care is needed if you are taking/using other medicines, as some could interact with amikacin for example:

diuretics (water tablets) such as furosemide and ethacrynic acid
other antibiotics that can affect your kidneys, hearing or balance
anaesthetics or muscle-relaxing drugs

indomethacin (an anti-inflammatory medicine)

other antibiotics called beta-lactamases such as penicillins

cephalosporins

bisphosphonates; drugs used to treat loss of bone mass

vitamin B1 (thiamine)

platinum compounds used in chemotherapy such as cisplatin

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness) which may lessen your ability to do so.

Important information about some of the ingredients of Amikacin Injection This medicine contains sodium metabisulphite, which may rarely cause hypersensitivity (severe allergy) reactions and bronchospasm (breathing difficulties).

This medicinal product contains less than 1 mmol (23 mg) sodium per dose, i.e. essentially 'sodium free'.

3. How to use amikacin injection

This medicine is usually injected into a muscle. It may also be given into a vein, either as an injection or (following dilution) as an infusion (drip).

Amikacin can also be given into the peritoneum (abdominal cavity) during surgery, and can be used to wash out abscess cavities, the lung cavity and brain cavities.

Your doctor will ensure you are well hydrated before and during treatment.

Dose

Your doctor will work out the correct dose of amikacin for you and how often it must be given. This may require blood tests before treatment.

The dose will depend upon your age, the infection you have, how well your kidneys are working, if you have poor hearing and any other medicines you may be taking.

It will usually be given to you two or three times a day, for up to 10 days. Adults and children over 12 years: The usual dose is 15 mg per kg per day which is administered as a single dose or divided into two equal doses of 7.5 mg per kg administered every 12 hours. The total dose should not exceed 1.5 g. When treatment is given in to a vein it is usually administered over a 30 to 60 minute period.

Children up to 12 years: The usual dose is 15 – 20 mg per kg of body weight once a day or divided into two equal doses of 7.5 mg per kg which is administered every 12 hours.

Neonates: The initial dose is 10 mg per kg of body weight followed by 7.5 mg per kg every 12hours.

Premature infants: The recommended dosing in premature babies is 7.5 mg per kg every 12hours.

During treatment you may undergo blood tests and be asked to provide urine samples. You will possibly also have hearing tests before and during treatment to look for signs of side effects. Your doctor may change your dose depending upon the results of these tests.

If you are given too much or too little Amikacin Injection This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible sideeffects

Like all medicines, amikacin can cause side effects, although not everybody gets them.

If any of the following happens, tell your doctor immediately as these are all serious. You may need urgent medical attention or hospitalisation.

Rare side-effects

which may affect less than 1 person in 1000 are listed below:

ringing in your ears or loss of hearing

decrease in the amount of urine you produce

Not known; numbers of sufferers cannot be estimated from available data are listed below:

severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

paralysis

deafness

sudden loss of breathing

severe kidney failure

These are serious side effects. You may need urgent medical attention. If any of the following happens, tell your doctor as soon as possible:

Uncommon side-effects which may affect more than 1 person in 1000 are listed below:

skin rash
nausea and vomiting
an excessive build up of bacteria or yeast which are resistant to amikacin

Rare side-effects

- which may affect less than 1 person in 1000 are listed below:
- dizziness or vertigo (spinning sensation)
- headache
- fever
- unusually low amount of red blood cells in the blood (anaemia) or excessive amounts of the white blood cells known as eosinophils in the blood (eosinophilia)
- low levels of magnesium in the blood
- abnormal tingling or 'pins and needles' sensation
- muscle tremors
- joint pain
- low blood pressure
- itching or hives

Amikacin may lead to changes in your kidney function. Your doctor may take blood and urine samples to monitor for changes such as increased levels of creatinine or nitrogen in the blood and protein or red/white blood cells in urine. Your doctor may also ask you to undergo hearing tests.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store amikacin injection

Keep out of the reach and sight of children

Expiry

This medicine must not be used after the expiry date which is stated on the vial and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

The vials should be stored at, or below, 25°C.

Unused portions of opened vials must not be stored for later use.

Prepared injections or infusions should be used immediately, however, if this is not possible they can be stored for up to 24 hours.

6. Further information

What Amikacin Injection contains

The active substance is amikacin. Each millilitre (ml) of solution contains 250 milligrams (mg) of amikacin (as amikacin sulphate).



The other ingredients are sodium citrate, sodium metabisulphite and Water for Injections. See section 2 for further information about sodium metabisulphite.

What Amikacin Injection looks like and contents of the pack
Amikacin Injection is a clear, colourless to pale yellow solution for injection which comes in glass containers called vials.

It may be supplied in packs containing 5 x 500 mg/2 ml vials

7.Manufactured in India by:

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