Package leaflet: Information for the user

Amikacin 250 mg/ml Solution for Injection/Infusion
amikacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amikacin is and what it is used for

Amikacin is an antibiotic of the aminoglycoside group which is used to treat severe infections in adults and children, including infants less than 4 weeks old.

Amikacin is used to treat infections of the respiratory tract and the lungs, the urinary and genital tracts, the gastrointestinal tract, inflammation of the inner lining of the heart (endocarditis), infected burns as well as bacterial blood infections associated with one of the infections mentioned. Amikacin may also be used to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.

2. What you need to know before you use Amikacin

Do not use Amikacin
- if you are allergic to amikacin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other aminoglycoside antibiotics.
- if you have bronchial asthma with a known allergy to sulfites.

If any of these conditions apply to you, contact your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before being given Amikacin, especially:
- if you have previous kidney problems (impaired kidney function), neuromuscular disease (Myasthenia gravis or Parkinson's disease) or hearing problems (inner ear damage).
- if you have just been treated with another aminoglycoside antibiotic.
- if you have any breathing difficulties (asthma).
- if you are allergic to sulfites.

In patients with kidney problems or those receiving either high doses or long term therapy, the risk of aminoglycoside antibiotic induced hearing impairment and kidney damage is increased.

If you experience ringing in the ears or any difficulty in balancing body movements, numbness, tingling of the skin, muscle twitches or spasms, tell your doctor immediately as these may be symptoms of nerve damage.

Your doctor may decide to evaluate and monitor your kidney function before beginning treatment and during treatment with amikacin. However, if you experience decreased urination, inform your doctor about it. You need to drink a lot of water during treatment with amikacin, especially when treatment lasts for longer than 5-7 days.

During treatment, your doctor may measure the level of amikacin in your blood and, if necessary, test your blood, liver, kidney, hearing and balance functions.
Special care should be taken in the treatment of premature babies and newborn infants.

Other medicines and Amikacin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Simultaneous and/or sequential treatment with medicines which are potentially toxic to the nervous system or the kidneys, such as cisplatin, cephalosporins, polymyxins, amphotericin B, cyclosporin, tacrolimus, bacitracin, cephaloridine, paramomycin, viomycin, colistin, vancomycin, ethacrynic acid, furosemide, other aminoglycosides or cytostatics, may lead to an exacerbation of toxicity.

Toxicity risks are higher in the elderly and patients who have lost a large amount of body fluid.

It is especially important that you tell your doctor if you have recently received an anaesthetic or are taking any of the following:
- Diuretics (water tablets or injection) e.g. furosemide.
- Antibiotics including penicillin-type antibiotics or cephalosporins.
- Inhalation narcotics (e.g ether, halothane).
- Muscle relaxants (e.g. d-tubocurarine, succinyl choline, decamethonium, atracurium, rocuronium, vecuronium) and volatile anaesthetics (increased risk of paralysis and respiratory paralysis [neuromuscular blockade]).
- Citrated blood transfusions (transfer of blood mixed with citrate to prevent its clotting).
- Amphotericin B, (used in the treatment of fungal infections).
- Bisphosphonates (used to treat osteoporosis or similar diseases) may lead to low blood calcium levels.
- Platinum compounds (used to treat cancer) which may increase the risk of kidney toxicity and possible hearing damage.
- Thiamine (vitamin B1), taken with amikacin, may lose its effectiveness.
- Any medicines which are bad for your kidneys or hearing.
- Indomethacin (an anti-inflammatory medicine)can increase the amount of amikacin which is absorbed by new born babies.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

If you are pregnant or think you may be pregnant, tell your doctor immediately, as amikacin should only be given during pregnancy if it is deemed absolutely necessary.

Tell your doctor if you are breast-feeding. It is unknown whether amikacin passes into the breast milk. Therefore, if treatment with amikacin is deemed necessary, breast milk must be pumped out and discarded.

Driving and using machines
The occurrence of side effects may interfere with your ability to drive and use machines.

Amikacin contains sodium metabisulfite
May rarely cause severe hypersensitivity reactions and bronchospasm.

Sulphite hypersensitivity is generally rare and more frequent in asthmatics than non-asthmatics. Sulphite hypersensitivity is rare and probably low in the general population.

Amikacin contains sodium
This medicine contains 14.92 mg sodium (main component of cooking/table salt) in each 2 ml vial. This is equivalent to 0.75 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Amikacin

Amikacin is given via an injection/infusion into either a muscle or a vein 2 to 3 times daily. Your doctor will adjust the dose of amikacin depending on the severity of your infection, the sensitivity of the disease-causing bacteria, your kidney function, your age and your body weight.

The treatment duration is generally 7 to 10 days.

If you are given more Amikacin than you should
Overdose may possibly result in toxic effects on the kidney, hearing and nervous system (neuromuscular blockade).

If you have any further questions on the use of this medicine, ask your doctor or a nurse.

4. Possible side effects

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

Common (may affect up to 1 in 10 people)
- ringing in the ears (tinnitus)
- hearing impairment, inner ear damage
- problems with kidney function
- decreased urinary excretion (oliguria)

Uncommon (may affect up to 1 in 100 people)
- infections with resistant bacteria or yeasts
- feeling sick (nausea)
- being sick (vomiting)
- rash

Rare (may affect up to 1 in 1,000 people)
- reduced red blood cell count (erythrocytopenia)
- an increase in white blood cell subset
- a deficiency in certain white blood cells (leukopenia)
- severe platelet loss (thrombocytopenia)
- low levels of magnesium in the blood
- tremors
- sensory disturbances
- headache
- balance disorders
- blindness or other problems with your vision
- changes in the area of the retina of your eye(s) (retinopathy)
- low blood pressure
- inflammation of vein walls (phlebitis)
- itching, hives, joint pain (arthralgia)

- muscle twitching (myokymia)
- fever, changes in liver function
- increased heart rate
- inflammation of the heart muscle (myocarditis)

Not known (frequency cannot be estimated from the available data)
- allergic reaction (sometimes severe)
- signs of muscular weakness caused by nerve damage or disease (paresis)
- deafness (cochlear damage), numbness or numb feeling
- paralysis of the respiratory (breathing) system
- temporary stopping of breathing (apnea)
- breathing difficulties due to narrowing of the respiratory (breathing) tract (bronchospasm)
- sudden kidney failure
- increase in serum creatinine (metabolic product used to measure renal function)
- excretion of albumin protein in the urine (albuminuria)
- increased concentration of nitrogen containing compounds in the blood (azotemia)
- red and/or white blood cells in the urine
- pain at the injection site

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amikacin

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

Do not use this medicine after the expiry date which is stated on the label, carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Intended for single use. To be administered immediately after dilution. Residual quantities are to be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 Amikacin contains

- The active substance is amikacin (as sulfate). Each ml contains 250 mg of amikacin (as sulfate).
- Each 2ml vial contains 500mg of amikacin (as sulfate).
- The other ingredients are sodium metabisulfite, sodium citrate, sulfuric acid and water for injections (see section 2, *"Amikacin contains sodium metabisulfite"* and *"Amikacin contains sodium"*).

What Amikacin looks like and contents of the pack

Amikacin (250 mg/ml) is available as a colourless or pale yellow transparent solution, practically free from visible particles, packed in a 2 ml clear Type-I glass vial with bromobutyl rubber stoppers and an aluminum cap with plastic flip-off.

2 ml (500 mg): 1, 5 and 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Neon Healthcare Ltd.
8 The Chase, John Tate Road, Hertford, SG13 7NN, UK

Manufacturer
Rafarm S.A.
Thesi Pousi-Xatzi Agiou Louka, Paiania-Attiki, 19002, P.O. Box 37, Greece

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for healthcare professionals only (see section 3):

How to prepare and administer Amikacin solution for injection/infusion

IM use or IV use after dilution.

Amikacin solution for injection/infusion is intended for single use. Residual quantities are to be discarded. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Only clear solution free from particles and discoloration should be used.

Amikacin should not be physically premixed with other drugs, but should be administered separately according to the recommended dose and route.

In paediatric patients the amount of diluents used will depend on the amount of amikacin tolerated by the patient. The solution should normally be infused over a 30 to 60-minute period. Infants should receive a 1 to 2-hour infusion.

The solution for intravenous use is prepared by adding the desired dose to 100mL or 200mL of sterile diluent such as normal saline or 5% dextrose in water or any other compatible solution. The solution is administered to adults over a 30 to 60-minute period.

Aseptic techniques must be followed during preparation of the infusion. The infusion must be conducted according to standard medical practice.

How to store Amikacin solution for injection/infusion

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and vial after EXP.
- The unopened vial does not require any special storage conditions.
- Intended for single use. To be administered immediately after dilution. Residual quantities are to be discarded.
- After dilution, chemical and physical in use stability has been demonstrated for 2 hours at room temperature (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, unless dilution has taken place in controlled and validated aseptic conditions