PACKAGE LEAFLET

Package leaflet: Information for the user

Amikacin 250mg/ml Solution for Injection/Infusion

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 used to treat serious infections in adults and children including, infants less than 4 weeks old.

Areas of application include infections of the respiratory tract and the lungs, the urinary and genital tract, the gastrointestinal tract, inflammation of the inner lining of the heart (endocarditis), infected burns as well as bacterial infections of the blood 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.

Warnings and precautions

Please talk to your doctor or pharmacist before taking Amikacin, especially

- if you have kidney problems (impaired renal function)
- if you have a muscular disorder (e.g. Parkinson's disease)
- if you have hearing problems (inner ear injury);
- if you have balance disorders
- if you are elderly
- if you suffer from dehydration
- if you are receiving concomitant anaesthetics (narcotics), neuromuscular blocking agents (such as suxamethonium, dexamethasone, atracurium, rocuronium or vecuronium) or a large blood transfusion (where citrate is added);
- if you are pregnant or breastfeeding;

- if the patient is a premature or newborn child, the excretion of this drug may be reduced due to the fact that kidney function is not fully developed;
- if you or your family members have a mitochondrial mutation disease (a genetic condition) or loss of hearing due to antibiotic medicines, you are advised to inform your doctor or pharmacist before you take an aminoglycoside; certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before administration of Amikacin.

Other medicines and Amikacin

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription.

Simultaneous administration of medicines which are potentially toxic to the inner ear or to the kidneys such as cephalosporins may lead to an exacerbation of renal toxicity. Amikacin given with penicillin or cephalosporin via other routes of administration may reduce the effectiveness of the preparation. Indomethacin may increase plasma levels of amikacin in neonates.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or plan to have a baby, consult your doctor before using this medicine

Pregnancy
The safety of the medicine in pregnant women has not been confirmed and therefore Amikacin should only be used during pregnancy when absolutely necessary.

Breast-feeding
It is not known whether amikacin passes into breast milk. Breastfeeding is not recommended during treatment. Therefore, talk to your doctor if breastfeeding or the treatment should be discontinued.

Driving and using machines

If you suffer from side effects such as dizziness, be especially careful when driving vehicles or operating machinery.

Important information about some of the ingredients of Amikacin

Amikacin contains sodium metabisulfite which may rarely cause severe allergic (hypersensitivity) reactions and difficulty in breathing or wheezing (bronchospasm).

Sulfite sensitivity is generally uncommon and more frequent in asthmatics than non-asthmatics.

2 ml vial
This medicine contains less than 1 mmol sodium (23mg) per 2ml vial, that is to say essentially ‘sodium-free’.

4 ml vial
This medicine contains 26.65 mg sodium (main component of cooking/table salt) in each 4ml vial. This is equivalent to 1.33% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Amikacin

Amikacin is given as an injection into a muscle or as an intravenous infusion over 30-60 minutes. The dose of Amikacin will be decided by your doctor depending on the severity of your infection, the sensitivity of the pathogen, your kidney function, your age and your body weight.

For children, the solution is normally given as an infusion over 30-60 minutes and for infants over 1-2 hours.

If you have received more Amikacin than you should

If you think you have received too much Amikacin, contact your doctor.

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

4. Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)

Common: (may affect up to 1 to in 10 people)

- dizziness
- balance disorder associated with the inner ear (vestibular disorders) with nausea
- protein in the urine

Uncommon: (may affect up to 1 in 100 people)

- super infections with resistant bacteria or yeasts
- feeling sick (nausea) or being sick (vomiting)
- elevation of liver enzymes (detected in blood test)
- rash

Rare (may affect up to 1 in 1,000 people)

- looking pale and feeling tired (anaemia)
- a deficiency in white blood cells (granulocytopenia, leukopenia)
- a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- low levels of magnesium in the blood (hypomagnesemia)
- tremors
- tingling or numbness (paraesthesia)
- headache
- balance disorders
- blindness
- blood flow to the retina is blocked causing blurry vision and possibly blindness (retinal infarction)

- ringing in the ears (tinnitus), hearing loss
- low blood pressure (hypotension)
- muscle weakness (hypotonia)
- inflammatory condition that causes blood clots to form in the veins (thrombophlebitis)
- increased heart rate (tachycardia)
- inflammation of the heart muscle (myocarditis)
- severe itching (pruritus)
- skin rashes with the formation of wheals (urticaria)
- joint pain (arthralgia)
- muscle contractions
- decreased production of urine (oliguria)
- increase of creatinine in the blood (azotemia)
- kidney disorder causing too much albumin in the urine (albuminuria)
- fever

Not known (frequency cannot be estimated from the available data):
- rapid onset muscle weakness (acute muscular paralysis)
- deafness
- throat relaxes and collapse causing a total blockage of the airway (apnoea)
- breathing difficulties or wheezing (bronchospasm)
- sudden kidney failure, toxicity in the kidneys
- 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 at 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 carton and vial after 'EXP'. The expiry date refers to the last day of that month.

The unopened vial does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Amikacin contains

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

Each 2ml vial contains 500mg of amikacin (as sulphate).

Each 4ml vial contains 1g of amikacin (as sulphate).

• The other ingredients are sodium metabisulfite (E223), sodium citrate dihydrate, sulfuric acid and water for injection.

What Amikacin looks like and contents of the pack

Amikacin 500mg/2ml (250mg/ml) is available as a clear, colourless to light straw-coloured solution, packed in a 2ml clear Type-I glass vial with a dark grey, chlorobutyl rubber stopper and a flip off seal.

2 ml (500 mg): 1 and 5 vials

Amikacin 1g/4ml (250mg/ml) is available as a clear, colourless to light straw-coloured, solution, packed in a 5ml clear Type-I glass vial with a dark grey, chlorobutyl rubber stopper and a flip off seal.

4 ml (1,000 mg): 1 and 5 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturer[1]

Emcure Pharma UK Limited
Basepoint Business Centre
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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

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

[1] Only actual manufacturer stated on printed leaflet.

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.

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 diluent 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.
- After dilution, chemical and physical in use stability has been demonstrated for 36 hours at 25°C, 30 days at -15°C and 60 days at 4°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°C to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.