PACKAGE LEAFLET: INFORMATION FOR THE USER

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Amikacin 250 mg/ml Solution for Injection or Infusion

Amikacin

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 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 excipient of this medicine (listed in section 6);
- if you are allergic to other aminoglycoside antibiotics;

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Amikacin:
- if you have previous kidney problems (renal dysfunction), neuromuscular disease (Respiratory paresis, 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 induced hearing impairment and kidney damage is increased.
- if you experience ringing in ears or any difficulty in balancing during body movements, inform your doctor immediately as these may be symptoms of nerve damage.
- if you experience any numbness, tingling of skin or muscle twitches or spasms, contact your doctor as these may be symptoms of nerve damage.
- 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.

Your kidney function may be evaluated before beginning treatment and monitored during treatment with Amikacin as per the physician's discretion.

However, if you experience decreased urination, inform your doctor. Patients need to drink a lot of water during treatment with amikacin, especially when used for longer than 5-7 days.

During therapy, 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 administration of medicines which are potentially toxic to the nervous system or the kidneys such as platinum compounds, cephalosporins, polymyxins, amphotericin B, cyclosporin, tacrolimus, bacitracin, cephaloridine, paramomycin, viomycin, colistin, vancomycin, ethacrynic acid, furosemide, other aminoglycosides, cephalosporins or cytostatics, may lead to an exacerbation of toxicity.

Other toxicity risks include an advanced age and dehydration.

It is especially important that you tell your doctor if you have recently received an anaesthetic or are taking any of the following:
- Diuretics e.g. furosemide (water tablets or injection)
- 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
- 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. (increased risk of kidney toxicity and possible hearing damage)
- Thiamine (Vitamin B1). If taken with amikacin, it may lose its effectiveness.
- Any medicines which are bad for your kidneys or hearing.
- Indomethacin (an anti-inflammatory medicine). This 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 for advice before taking this medicine.

Tell your doctor immediately if you are pregnant or think you may be pregnant, as Amikacin should only be taken during pregnancy if it is deemed absolutely necessary.

Tell your doctor if you are breast-feeding. It is unknown whether or not amikacin passes through into breast milk. Therefore, if treatment with amikacin is deemed necessary, breast milk must be pumped out and rejected.

Driving and using machines

The occurrence of side effects may interfere with the ability to drive vehicles and operate 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).

Sulphite hypersensitivity is generally uncommon and more frequent in asthmatics than nonasthmatics.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

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

Amikacin 250 mg/ml Solution for Injection or Infusion

How to prepare and administer Amikacin solution for injection or infusion

IM use or IV use after dilution.

Amikacin solution for injection or 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 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.

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

3. HOW TO TAKE AMIKACIN

Amikacin is given via an injection into either a muscle or vein two to three times daily. The dose of Amikacin will be adjusted by your physician depending on the severity of your infection, the sensitivity of the pathogen, your kidney function, your age and your body weight.

The treatment duration is generally 7 to 10 days. The total daily dose by all routes of administration should not exceed 15-20 mg/kg/day.

Adults and children over 12 years:
The usual dose is 15 mg/kg/day which is given once a day or divided into two doses which are given twice a day.

Children aged 4 weeks to 12 years:
The usual dose is 15 – 20 mg/kg/day which is given once a day or divided into two doses which are given twice a day.

Neonates:
The usual dose is initially 10 mg/kg followed by 7.5 mg/kg which is given twice a day.

Premature infants:
The usual dose is 7.5 mg/kg twice a day.

Elderly:
Kidney function should be assessed and dose adjusted as described under impaired kidney function.

Life-threatening infection and/or those caused by Pseudomonas:
The doses may be increased to 500mg every eight hours but should not exceed 1.5 g/day or be administered for a period longer than 10 days.

Urinary tract infections:
The usual dose is 7.5 mg/kg/day twice a day.

Impaired kidney function:
The daily dose should be reduced and/or the interval between doses increased to avoid build up of drug. The doses may be increased in certain infections.

You may require hearing and kidney tests while receiving Amikacin as well as blood tests to check the amount of amikacin received.

If you take more Amikacin than you should
Ominous danger of overdose is a possibly kidney (renal), hearing and neuro-toxic effect (neuromuscular blockade).
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

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

Common: (may affect 1 to less than 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 (Anaemia)
- an increase in white blood cell subset (eosinophilia)
- a deficiency in certain white blood cells (granulocytopaenia)
- severe platelet loss (thrombocytopaenia)
- low levels of magnesium in the blood (Hypomagnesaemia)
- tremors
- pins and needles (paraesthesia)
- 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 (thrombophlebitis)
- itching, hives, joint pain (arthralgia)
- muscle twitching
- 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 Urine (albuminuria),
- increased concentration of nitrogen containing protein products 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 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 carton after 'EXP'.
The expiry date refers to the last day of that month.
This medicinal product 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).
- 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 yellow coloured solution, packed in a 4ml clear Type-I glass vial with a grey, bromobutyl rubber stopper and a aluminium cap with a plastic flip off seal.
2 ml (500 mg): 10 and 5 vials
Not all pack sizes may be marketed.

Marketing Authorisation Holder
hameln pharma ltd
Nexus, Gloucester Business Park,
Gloucester, GL3 4AG,
United Kingdom

Manufacturer
ANFARM HELLAS S.A.,
61st km NAT.RD. Athens-Lamia,
Schimatari Viotias 32009,
Greece

This leaflet was last revised in April 2023.

3243/17/23

How to store Amikacin solution for injection or 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 in 0.9% sodium chloride and 5% glucose solutions chemical and physical in-use stability has been demonstrated for 24 hours at a temperature not exceeding 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°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.