Package leaflet: Information for the user

Amikacin 250 mg/ml Injection

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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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 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.

Warnings and precautions

Talk to your doctor before using 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 or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cells which help make energy) or loss of hearing due to antibiotic medicines;

certain mitochondrial mutations may increase your risk of hearing loss with this product
- if you have a known allergy to sulphites

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

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

Other medicines and Amikacin Injection
Tell your doctor if you are taking, have recently taken or might take/use any 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 or cephalosporins
- bisphosphonates; drugs used to treat loss of bone mass
- vitamin B1 (thiamine)
- platinum compounds used in chemotherapy such as cisplatin

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. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

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.

Amikacin Injection contains sodium metabisulphite
This may rarely cause hypersensitivity (severe allergy) reactions and bronchospasm (breathing difficulties).

Amikacin Injection contains sodium
Amikacin 250 mg/ml injection contains 12.88 mg of sodium (main component of cooking/table salt) in each 2 ml vial. This is equivalent to 0.6% of the recommended maximum daily dietary intake of sodium for an adult.

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

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 side effects

Like all medicines, this medicine 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 may affect up to 1 in 1,000 people are listed below:

- ringing in your ears or loss of hearing
- decrease in the amount of urine you produce

Not known: frequency 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 may affect up to 1 in 100 people are listed below:

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

Rare side-effects may affect up to 1 in 1,000 people 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. 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 Injection

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

Expiry
Do not use this medicine after the expiry date which is stated on the vial and carton after EXP. 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. Contents of the pack and other 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 and sodium.

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

Marketing Authorisation Holder and Manufacturer

Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK

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Amikacin 250 mg/ml Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Amikacin is incompatible with some penicillins and cephalosporins, amphotericin chlorothiazide sodium, erythromycin gluceptate, heparin, nitrofurantoin sodium, phenytoin sodium, thiopentone sodium and warfarin sodium, and depending on the composition and strength of the vehicle, tetracyclines, vitamins of the B group with vitamin C, and potassium chloride.

At times, amikacin may be indicated as concurrent therapy with other antibacterial agents in mixed or superinfections. In such instances, amikacin should not be physically mixed with other antibacterial agents in syringes, infusion bottles or any other equipment. Each agent should be administered separately.

Instructions for use and handling
Single use only

Discard any unused contents

The solution may darken from colourless to a pale yellow but this does not indicate a loss of potency.

If required, suitable diluents for intravenous use are normal saline or 5% dextrose in water.

Amikacin in concentrations of 0.25% (2.5 mg/ml) may be used satisfactorily as an irrigating solution in abscess cavities, the pleural space, the peritoneum and the cerebral ventricles.

In use storage precautions
Following 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 above 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.

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