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.

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.

1. WHAT IS IN THIS LEAFLET
1.1. Amikacin is an antibiotic used to treat serious infections in all categories of patients including infants less than 4 weeks old. Amikacin affects only certain bacteria causing infections, which are resistant to other antibiotics. Amikacin works by killing the bacteria and reducing the number of bacteria in your body.

1.2. If you are allergic to amikacin or any of the other ingredients in this product (listed in section 6), do not use Amikacin.

1.3. If you have any allergies or other medical conditions, make sure your doctor is aware of them before you start taking Amikacin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AMIKACIN
2.1. Tell your doctor or pharmacist if you are pregnant or breast-feeding. This medicine may pass into the womb and breast milk in small amounts. Please consult your doctor if you are pregnant or if you are planning a pregnancy.

2.2. Tell your doctor if you are taking any other medicines, including those bought without a prescription. Some medicines can affect the amount of Amikacin in your blood, or Amikacin may affect the way your body deals with other medicines. In particular:

- **Diuretics** (water tablets or diuretics; this can increase the amount of Amikacin which is absorbed by new born babies.)
- **Antibiotics including penicillin-type antibiotics or cephalosporins**.
- **Other medicines and Amikacin**

- **Indomethacin** (an anti-inflammatory drug) which may increase the amount of Amikacin which is absorbed by new born babies.
- **Platnum compounds**. (increased risk of kidney toxicity and possible hearing damage)
- **Thiamine (Vitamin B1)**. If taken with Amikacin, it may lose its effectiveness.
- **Other medicines**. In a minority of cases, these medicines may interfere with the ability to drive vehicles and operate machines.

3. HOW TO USE AMIKACIN
3.1. Amikacin is for injection. It is given under the skin (subcutaneously), into a vein (intravenously) or into a muscle (intramuscularly). Before any injection, your doctor or pharmacist will teach you how to give yourself the injection or how to do injection therapy. If the injection is given into a vein, the injection will be made slowly into the vein. Aseptic techniques must be followed during preparation of the infusion. The infusion must normally be infused over a 30 to 60-minute period. Infants should receive a 1 to 2-hour infusion.

3.2. Amikacin solution for intravenous use is prepared by adding the desired dose to 100mL or 200mL of sodium chloride solution for injection in 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.

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

Amikacin 300 mg/ml Solution for Injection or Infusion
This medicine contains less than 1 mg/ml sodium from 2 ml 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 doctor in relation to 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 usual daily dose of Amikacin in adults should not exceed 16-20 mg/kg/day.

Amikacin in 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.

Note:
The usual dose is initially 10 mg/kg followed by 7.5 mg 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 500 mg every four 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 the injections should be at least 12 hours of 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 in your body.

If you take more Amikacin than you should:
Ominous danger of overdose is a possibly fatal complication (neuromuscular blockade).

If not used immediately, in-use storage and conditions prior to use are the same as stated below.

This medicine contains less than 1 mmol (23 mg) of sodium from 2 ml vial and is essentially ‘sodium-free’.

The active substance is amikacin (as dihydrate, sodium dihydrogenphosphate, sulfuric acid and water for injection).

Amikacin 500mg/2ml (250mg/ml) is available as a clear, colourless to light yellow coloured solution in 2 ml vials with a grey, bromobutyl rubber stopper and a as a clear, colourless to light yellow coloured solution in 2 ml vials with a grey, bromobutyl rubber stopper and a plastic sealing disc.

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.

Common: (may affect 1 to less than 10 people):
• ringing in the ears (tinnitus)
• hearing impairment, inner ear damage
• loss of taste
• decreased urinary excretion (oliguria)

Uncommon: (may affect up to 1 in 100 people):
• Infections with resistant bacteria or yeasts
• feeling sick (vomiting)
• rash
• muscle or vein two to three times daily.

Rare (may affect up to 1 in 1,000 people):
• reduced red blood cell count (Anaemia )
• an increase in white blood cell count (leucocytosis)
• a deficiency in certain white blood cells (granulocytopenia)
• severe platelet loss (thrombocytopenia)
• low levels of magnesium in the blood (Hypomagnesaemia)
• tinnitus
• pins and needles (paraesthesia)
• headache
• abdominal disorders
• blindness or other problems with your vision
• changes in the area of the retina of your eyes (retinopathy)
• low blood pressure
• inflammation of the muscles (myositis)
• itching, rashes, joint pain (arthralgia)
• allergic reaction
• fever, changes in liver function
• increased heart rate

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Amikacin contains
The active substance is amikacin (as dihydrate).

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

The other ingredients are sodium chloride, sodium dihydrogenphosphate, dihydrogen monophosphate, sucrose 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 4-ml clear Type I glass vial with a grey, bromobutyl rubber stopper and an aluminium cap with a pink flat slipping off seal.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
hamel pharm ltd
Nexus, Gloucester Business Park, Gloucester, GL3 4AG, United Kingdom

Manufacturer
ANFARM HELLAS S.A., 3243-2 km NAT.RD., Athens-Lamia, 3243-2 km NAT.RD.
Schimatari Viotias 32009, Greece

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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
• paralysed of the respiratory (breathing) system
• temporary stopping of breathing (apnea)
• breathing difficulty 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.

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 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.