

## PATIENT COUNSELLING INFORMATION

### <sup>Rx</sup> Amikacin Injection IP

#### MIKACIN<sup>®</sup> INJ

#### **Read the entire leaflet carefully before you start taking this medicine:**

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

#### **1. What is Mikacin<sup>®</sup> injection and what is it used for?**

Mikacin<sup>®</sup> injection contains the antibiotic Amikacin which comes under the antibiotic class ‘aminoglycosides’.

Mikacin<sup>®</sup> injection is used in the treatment of serious infections caused by bacteria sensitive to Amikacin.

#### **2. What you need to know before you take Mikacin<sup>®</sup> injection?**

Before taking Mikacin<sup>®</sup> injection, tell your doctor:

- if you have shown signs of hypersensitivity (severe allergy) to Amikacin, or any of the other ingredients.
- 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 Mikacin<sup>®</sup> 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 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 Mikacin<sup>®</sup> 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, think you may be pregnant, planning to have a baby or breast-feeding your 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.

### **3. How to take Mikacin<sup>®</sup> 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. 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 once or twice daily, 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. When Mikacin<sup>®</sup> injection is administered in to a vein it is usually 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. What are the possible side effects of Mikacin<sup>®</sup> injection?**

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 buildup 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.**

### **5. How to store Mikacin<sup>®</sup> injection?**

**Store in a cool dry place. Do not allow to freeze.**

Keep out reach of children.

Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

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*For further information please write to :*



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