AMIKACIN



Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Amikacin Medsurge?

Amikacin Medsurge contains the active ingredient amikacin sulfate equivalent to amikacin activity 500 mg (500,000 IU). Amikacin is used to treat serious bacterial infections.

For more information, see Section 1. Why am I using Amikacin Medsurge? in the full CMI.

2. What should I know before I use Amikacin Medsurge?

Do not use if you have ever had an allergic reaction to amikacin sulphate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Amikacin Medsurge? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Amikacin Medsurge and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Amikacin Medsurge?

• Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function.

More instructions can be found in Section 4. How do I use Amikacin Medsurge? in the full CMI.

5. What should I know while using Amikacin Medsurge?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using amikacin If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given amikacin
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Amikacin Medsurge affects you
Looking after your medicine	 Amikacin Injection will usually be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C

For more information, see Section 5. What should I know while using Amikacin Medsurge? in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse if you notice any of the following and they worry you: Pain at the injection site, feeling sick, decreased appetite, headache, nausea and vomiting, fever. These side effects are usually mild.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Amikacin Medsurge

Active ingredient(s): amikacin sulphate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Amikacin Medsurge. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Amikacin Medsurge.

Where to find information in this leaflet:

- 1. Why am I using Amikacin Medsurge?
- 2. What should I know before I use Amikacin Medsurge?
- 3. What if I am taking other medicines?
- 4. How do I use Amikacin Medsurge?
- 5. What should I know while using Amikacin Medsurge?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Amikacin Medsurge?

Amikacin Medsurge contains the active ingredient amikacin sulfate equivalent to amikacin activity 500 mg (500,000 IU). Amikacin is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced amy-noe-GLY-koe-sides). It is used to treat serious bacterial infections. Amikacin works by killing bacteria or preventing their growth. Amikacin is used to treat serious bacterial infections.

Your doctor may have prescribed amikacin for another reason.

Ask your doctor if you have any questions about why amikacin has been prescribed for you.

This medicine is available only with a doctor's prescription.

2. What should I know before I use Amikacin Medsurge?

Warnings

Do not use Amikacin Medsurge if:

- you are allergic to amikacin sulphate, or any of the ingredients listed at the end of this leaflet.
 Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

You must not be given Amikacin Injection if you have experienced serious reactions (such as hearing loss or kidney problems) to amikacin, streptomycin, gentamicin, tobramycin, kanamycin, polymyxin B, colistin, cefaloradine, viomycin, or neomycin in the past.

 You must not be given Amikacin Injection if you have myasthenia gravis, a condition in which the muscles become weak and tire easily.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

 Amikacin may affect your developing baby if you are given it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Amikacin passes into breast milk.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, in particular any other antibiotics
- sulfites / sulfates
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- · kidney disease
- hearing or if you or your family have a mitochondrial mutation disease, or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease).

If you have not told your doctor or pharmacist about any of the above, tell them before you are given amikacin.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and amikacin may interfere with each other. These include:

- fluid tablets (e.g. furosemide (frusemide), etacrynic acid)
- platinum compounds used to treat cancer, such as cisplatin
- some other antibiotics (e.g. vancomycin, clindamycin, colistin, bacitracin, paromomycin, polymyxin B, cefalosporins, penicillins, viomycin)
- amphotericin, a medicine used to treat some fungal infections
- some medicines used to help prevent organ transplant rejection or to treat certain problems with the immune system, e.g. ciclosporin, tacrolimus
- suxamethonium, a medicine used during surgery to relax muscles
- some general anaesthetic agents
- opioid analgesics (e.g. codeine, morphine, pethidine, fentanyl)
- thiamine (vitamin B1)
- bisphosphonates, medicines used to treat loss of bone mass
- indomethacin, an anti-inflammatory medicine.

These medicines may be affected by amikacin or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while receiving amikacin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Amikacin Medsurge.

4. How do I use Amikacin Medsurge?

How much to take / use

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function.

When to take / use Amikacin Medsurge

Amikacin injection is usually given as an injection into a muscle. Amikacin Injection can also be given as a slow injection into a vein (intravenously). Amikacin Injection must only be given by a doctor or nurse. Your doctor will decide what dose and how long you will receive Amikacin Injection. This depends on your infection and other factors, such as your weight. For most infections, Amikacin Injection is usually given in divided doses throughout the day.

If you use too much Amikacin Medsurge

As amikacin Injection is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience severe side effects, tell your doctor immediately or go to Emergency at the nearest hospital.

Symptoms of an amikacin overdose may include ringing in the ears, hearing difficulties, dizziness, fever, headache,

pins and needles in the hands and feet, problems with passing urine, and paralysis.

You should immediately:

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much atracurium besilate.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Amikacin Medsurge?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are being given Amikacin Injection.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Amikacin Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given amikacin.

If you become pregnant while being treated with Amikacin Injection, tell your doctor immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Amikacin Medsurge affects you.

As with other aminoglycoside medicines, amikacin may cause drowsiness, tiredness or dizziness in some people.

Make sure you know how you react to amikacin before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, tired or dizzy. If this occurs do not drive.

Looking after your medicine

 Amikacin Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Keep it where young children cannot reach it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
pain at the injection site	Speak to your
 feeling sick 	doctor if you
 decreased appetite 	have any of
headache	these less
 nausea and vomiting 	serious side
• fever.	effects and
	they worry you.

Serious side effects

Serious side effects	What to do
 dizziness, spinning sensation (vertigo) hearing problems, ringing or unusual sounds in the ears (tinnitus) loss of vision passing less urine than is normal, blood in the urine numbness, skin tingling, muscle twitching and convulsions, paralysis signs of an allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

7. Product details

This medicine is only available with a doctor's prescription.

What Amikacin Medsurge contains

Active ingredient (main ingredient)	amikacin sulfate
Other ingredients (inactive ingredients)	sodium citrate dihydrate, sodium metabisulfite,
Potential allergens	water for injection. none

Do not take this medicine if you are allergic to any of these ingredients.

What Amikacin Medsurge looks like

Amikacin Medsurge Injection comes in a glass vial containing a clear, colourless to pale yellow solution free from visible particulate matter (AUST R 401536). Amikacin Injection is available in the following strengths and pack size:

• 500 mg/2 mL x 5 vials

Who distributes Amikacin Medsurge

Medsurge Pharma Limited PO Box 331054 Takapuna Auckland 0622

Telephone: 0800 788 261

Marketed and Distributed by Medsurge Healthcare.



Telephone: 1300 788 261 Website: <u>www.medsurgehc.com</u>

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