

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr AMIKACIN SULFATE INJECTION USP

Amikacin Sulfate

250 mg / mL

Read this carefully before you start taking **Amikacin Sulfate Injection USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Amikacin Sulfate Injection USP**.

What is Amikacin Sulfate Injection USP used for?

Amikacin Sulfate Injection USP is used to treat certain serious bacterial infections:

- of the nose, throat, chest and lungs (respiratory tract)
- in the blood
- of the joints and bones
- of the kidneys and urinary bladder (urinary tract)
- of the lining of the abdomen (peritoneum)
- of the soft tissues

Antibacterial drugs like Amikacin Sulfate Injection USP treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, Amikacin Sulfate Injection USP should be used exactly as directed. Misuse or overuse of Amikacin Sulfate Injection USP could lead to the growth of bacteria that will not be killed by Amikacin Sulfate Injection USP (resistance). This means that Amikacin Sulfate Injection USP may not work for you in the future.

How does Amikacin Sulfate Injection USP work?

Amikacin Sulfate Injection USP is an antibiotic. It works by killing or slowing the growth of certain types of bacteria that cause the infection.

What are the ingredients in Amikacin Sulfate Injection USP?

Medicinal ingredient: Amikacin as amikacin sulfate.

Non-medicinal ingredients: sodium metabisulfite, sodium citrate dihydrate, sulfuric acid to adjust pH and water for injection.

Amikacin Sulfate Injection USP comes in the following dosage forms:

Amikacin Sulfate Injection USP is a sterile aqueous solution containing 250 mg/mL of amikacin as amikacin sulfate.

Do not use Amikacin Sulfate Injection USP if you:

- you are allergic to amikacin or any other ingredients in the drug (See What are the ingredients in Amikacin Sulfate Injection USP)
- you are sensitive or allergic to other aminoglycosides

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Amikacin Sulfate Injection USP. Talk about any health conditions or problems you may

have, including if you:

- have been or are being treated with other aminoglycosides.
- have drug allergies.
- have kidney problems.
- have hearing or balance problems.
- have myasthenia gravis (a muscle condition) or Parkinson's disease.
- are pregnant or planning to become pregnant.
- are breastfeeding or planning to breastfeed.
- have asthma.
- have sulfite sensitivity.

Other warnings you should know about:

- Amikacin Sulfate Injection USP and other similar aminoglycosides have been known to cause hearing and balance problems (ototoxicity) and kidney problems (nephrotoxicity). Your doctor will observe you carefully for warning signs of these events after giving you Amikacin Sulfate Injection USP.
- Your doctor may monitor the level of amikacin sulfate in your blood through blood tests, especially if you are taking, or have taken in the recent past, certain medications that can interact with Amikacin Sulfate Injection USP.
- The safety for treatment periods which are longer than 14 days has not been established.
- Amikacin Sulfate Injection USP, like many antibiotics, can cause *Clostridium difficile* colitis (bowel inflammation caused by a bacterial infection). If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this occurs, stop taking Amikacin Sulfate Injection USP and contact your doctor right away.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Amikacin Sulfate Injection USP:

- Other antibiotics such as other aminoglycosides (e.g. gentamicin, neomycin, streptomycin, tobramycin), cephalosporins, clindamycin, imipenem, polymixin B, bacitracin, cephaloridine, colistin, paromomycin, penicillins and vancomycin.
- Amphotericin B, a medicine used to treat severe fungal infections.
- Anti-cancer drugs, such as cisplatin.
- Potent diuretics, such as ethacrynic acid, furosemide and mannitol.
- Neuromuscular blocking agents (muscle relaxants such as tubocurarine, succinylcholine and decamethonium)
- Anesthetic agents such as those used during surgery.
- Any drug that may cause kidney or hearing problems.

How to take Amikacin Sulfate Injection USP:

Amikacin Sulfate Injection USP will be given to you by a healthcare professional either as an injection into a muscle or injection into a vein at a hospital or clinical setting.

Usual Dose:

Your doctor will decide the dose that is right for you based on your age, weight and other factors. If you have kidney problems, your doctor may adjust the dosage schedule to suit you.

The usual dose of Amikacin Sulfate Injection USP is 7.5 mg/kg of body weight, given every 12 hours, for a total daily dose of 15 mg/kg of body weight, over a period of up to 10 days.

Overdose:

If you think you have been given too much **Amikacin Sulfate Injection USP**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms

Missed Dose:

Amikacin Sulfate Injection USP is administered by a healthcare professional. If you think you have missed a dose talk to your healthcare professional.

What are possible side effects from using Amikacin Sulfate Injection USP?

These are not all the possible side effects you may feel when taking **Amikacin Sulfate Injection USP**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- rash
- nausea, vomiting
- allergic reaction, such as hives
- difficulty breathing
- headache
- pain at injection site
- fever
- hypotension
- anemia
- tremor
- joint pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Kidney Problems: blood in urine, change in frequency of urination or amount of urine, weakness, difficulty with breathing, drowsiness, increased thirst, loss of appetite, nausea, vomiting, fluid retention causing swelling of the legs, ankles or feet			√
Hearing Problems: trouble hearing or hearing loss with or without ringing in the ears, roaring in the ears, dizziness			√

UNKNOWN FREQUENCY Nervous System Problems: numbness, skin tingling, muscle twitching, convulsions, seizure, trouble breathing			√
Serious Allergic Reaction (hypersensitivity): swelling of the face, lips, tongue or throat, trouble breathing or swallowing, itching, hives, skin rash with or without blisters or peeling			√
Inner Ear Problems: loss of balance, dizziness or lightheadedness, sensation of spinning, feeling of constant movement of self or surroundings		√	
Clostridium difficile Colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Amikacin Sulfate Injection USP vials should be protected from light and stored at 15°C - 30°C.

Keep out of reach and sight of children.

If you want more information about Amikacin Sulfate Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.marcapharma.com, or by calling 1-855-627-2261.

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