

# Amikacin Kabi Solution for Infusion

## 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 being given Amikacin Kabi ?

Amikacin Kabi contains the active ingredient amikacin (as sulfate). Amikacin Kabi is an antibiotic used to kill bacteria or prevent their growth.

For more information, see Section [1. Why am I being given Amikacin Kabi?](#) in the full CMI.

### 2. What should I know before I am given Amikacin Kabi?

Do not use if you have ever had an allergic reaction to amikacin sulfate 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 am given Amikacin Kabi?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Amikacin Kabi 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 am I given Amikacin Kabi Injection ?

- Your doctor will decide what dose you will receive and how long you will receive it, depending on your condition and other factors, such as your weight and kidney function.
- For most infections, Amikacin Kabi is usually given in divided doses throughout the day.
- Amikacin Kabi is given as a slow injection into a vein (intravenously). Amikacin Kabi must only be given by a doctor or a nurse.

More instructions can be found in Section [4. How am I given Amikacin Kabi?](#) in the full CMI.

### 5. What should I know while being given Amikacin Kabi ?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or and pharmacist who is treating you that you are taking Amikacin Kabi.</li><li>• Before starting any new medicine, tell your doctor, dentist, or pharmacist that you are taking Amikacin Kabi.</li><li>• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Amikacin Kabi.</li><li>• Advise your doctor if you have side effects while being treated.</li><li>• If you become pregnant while being treated with Amikacin Kabi, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not miss any follow-up appointments with your doctor following treatment with Amikacin Kabi.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Amikacin Kabi may cause drowsiness, tiredness, or dizziness in some people. Make sure you know how you react to Amikacin Kabi before you drive a car, operate machinery, or do anything else that could be dangerous.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Amikacin Kabi will be stored in the pharmacy or on the ward. The solution for infusion is kept in a cool dry place, where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while being given Amikacin Kabi?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects are pain at the injection site, feeling sick, decreased appetite, nausea, vomiting, headache, and fever. Serious side effects include dizziness or spinning sensation, hearing problems, or ringing in the ears, loss of vision, passing less urine than is normal, blood in urine, numbness, skin tingling, muscle twitching and convulsions, or paralysis. Signs of an allergic reaction include 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.

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 Kabi

Active ingredient(s): amikacin (as sulfate)

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

- [1. Why am I being given Amikacin Kabi?](#)
- [2. What should I know before I am given Amikacin Kabi?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given Amikacin Kabi?](#)
- [5. What should I know while being given Amikacin Kabi?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given Amikacin Kabi?

**Amikacin Kabi contains the active ingredient amikacin (as sulfate).** Amikacin Kabi is an antibiotic that belongs to a group of medicines called aminoglycosides.

Amikacin Kabi works by killing bacteria or preventing their growth.

**Amikacin Kabi is used to treat serious bacterial infections.**

## 2. What should I know before I am given Amikacin Kabi?

### Warnings

**You must not be given Amikacin Kabi if:**

- you are allergic to amikacin sulfate or any of the ingredients listed at the end of this leaflet, other antibiotics, or other substances, such as foods, preservatives, or dyes.
- Always check the ingredients to make sure you can use this medicine.
- 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.
- you have experienced serious reactions (such as hearing loss or kidney problems) to amikacin, streptomycin, gentamicin, tobramycin, kanamycin, polymyxin B, colistin, cefaloridine, viomycin, or neomycin in the past.
- you have myasthenia gravis, a condition in which the muscles become weak and tire easily.
- you are pregnant or planning to become pregnant or are breastfeeding.

**Check with your doctor if you:**

- have any other medical conditions such as kidney disease, hearing disorders or muscular disorders (e.g., myasthenia gravis, Parkinson's disease).
- have hearing loss due to antibiotic medicine
- have mitochondrial mutation disease (certain mitochondrial mutations may increase your risk of hearing loss)
- have family members with mitochondrial mutation disease.
- your doctor may want to take special care if you have any of these conditions.
- take any medicines for any other condition, in particular antibiotics, or sulfates.

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

Tell your doctor if you are pregnant or intend to become pregnant.

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

You must not be given amikacin if you are breast feeding. Amikacin passes into breast milk.

## 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 may interfere with Amikacin Kabi and affect how it works.**

These include:

- fluid tablets (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, cephalosporins, penicillins, viomycin)
- amphotericin, a medicine used to treat some fungal infections
- suxamethonium, a medicine used during surgery to relax muscles
- some general anaesthetic agents
- opioid analgesics (e.g., codeine, morphine, pethidine, fentanyl)
- some medicines used to help prevent organ transplant rejection or to treat certain problems with the immune system, e.g., ciclosporin, tacrolimus

- bisphosphonates, medicines used to treat loss of bone mass
- thiamine (vitamin B1)
- indomethacin, an anti-inflammatory medicine

**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 Kabi.**

#### 4. How am I given Amikacin Kabi?

##### How much you will be given

- Your doctor will decide what dose and how long you will receive Amikacin Kabi.
- Your dose will be determined by your condition and other factors, such as your weight and kidney function.

##### How you will be given Amikacin Kabi

- You will receive Amikacin Kabi in the hospital.
- Amikacin Kabi is given as a slow infusion into a vein (intravenously)
- Amikacin Kabi must only be given by a doctor or a nurse.

##### How long Amikacin Kabi is given for

- Your doctor will decide what dose and how long you will receive Amikacin Kabi. This depends on your infection and other factors, such as your weight.
- For most infections, Amikacin Kabi is usually given in divided doses throughout the day.

##### If you are given too much Amikacin Kabi

As Amikacin Kabi 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 Accident and Emergency at the nearest hospital.

Symptoms of Amikacin Kabi overdose may include ringing in the ears, hearing difficulties, dizziness, fever, headache, pins and needles in the hand and feet and problems with passing urine, and paralysis.

If you think that you have been given too much Amikacin Kabi, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

#### 5. What should I know while being given Amikacin Kabi?

##### Things you should do

- Tell any doctor, dentist or pharmacist who is treating you that you are taking Amikacin Kabi.
- Before starting any new medicine, tell your doctor, dentist, or pharmacist that you are taking Amikacin Kabi.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Amikacin Kabi.
- Advise your doctor if you have side effects while being treated.
- If you become pregnant while being treated with Amikacin Kabi, tell your doctor immediately.

##### Things you should not do

- Do not miss any follow-up appointments with your doctor following treatment with Amikacin Kabi.

##### Driving or using machines

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

As with other aminoglycoside medicines, Amikacin Kabi may cause drowsiness, tiredness, or dizziness in some people. Make sure you know how you react to Amikacin Kabi 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 Kabi will be stored in the pharmacy or on the ward. The solution for infusion is kept in a cool dry place, where the temperature stays below 25°C.

#### 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
<ul style="list-style-type: none"> <li>• pain at the injection site</li> <li>• feeling sick</li> <li>• decreased appetite</li> <li>• nausea and vomiting</li> <li>• fever</li> <li>• headache</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>dizziness, spinning sensation (vertigo)</li><li>hearing problems or ringing in the ears (tinnitus)</li><li>Apnoea (a temporary stop in breathing.)</li><li>Bronchospasm (breathing difficulties due to narrowing of the respiratory (breathing) tract)</li><li>loss of vision</li><li>passing less urine than is normal</li><li>blood in the urine</li><li>numbness, skin tingling, muscle twitching and convulsions, paralysis</li><li>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</li></ul>	<b>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.</b>

**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.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Amikacin Kabi contains

Each mL of Amikacin Kabi solution for infusion contains amikacin sulfate equivalent to 5 mg of amikacin activity.

Each mL of Amikacin Kabi solution for infusion contains 3.54 mg sodium (equivalent to 0.154 mmol sodium).

<b>Active ingredient (main ingredient)</b>	amikacin (as sulfate)
<b>Other ingredients (inactive ingredients)</b>	sodium chloride sodium hydroxide hydrochloric acid water for injections
<b>Potential allergens</b>	sulfites

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

Amikacin Kabi Solution for Infusion does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes.

### What Amikacin Kabi looks like

Amikacin Kabi is a clear, colourless aqueous solution.

The solution for infusion is presented in bottles of low-density polyethylene closed with a cap containing a rubber disc to allow insertion of the needle.

Pack sizes\*

10 x 50 mL (250 mg amikacin)	AUST R 408399
10 x 100 mL (500 mg amikacin)	AUST R 408406
10 x 200 mL (1000 mg amikacin)	AUST R 408407

\*Not all pack sizes may be marketed.

### Who distributes Amikacin Kabi

#### Sponsor

Fresenius Kabi Australia Pty Limited  
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Australia  
Telephone: (61-2) 9391 5555

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