

# Amikacin SXP

## 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 SXP?

AMIKACIN SXP contains the active ingredient amikacin sulfate. AMIKACIN SXP is an antibiotic used to kill bacteria or prevent their growth.

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

### 2. What should I know before I am given AMIKACIN SXP?

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 SXP?](#) in the full CMI.

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

Some medicines may interfere with AMIKACIN SXP 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 SXP?

- 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 SXP is usually given in divided doses throughout the day.
- AMIKACIN SXP is usually given as an injection into a muscle. It can also be given as a slow injection into a vein (intravenously). AMIKACIN SXP must only be given by a doctor or a nurse.

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

### 5. What should I know while being given AMIKACIN SXP?

<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 SXP.</li><li>• Before starting any new medicine, tell your doctor, dentist or pharmacist that you are taking AMIKACIN SXP.</li><li>• If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given AMIKACIN SXP.</li><li>• Advise your doctor if you have side effects while being treated.</li><li>• If you become pregnant while being treated with AMIKACIN SXP, 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 SXP.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• AMIKACIN SXP may cause drowsiness, tiredness or dizziness in some people. Make sure you know how you react to AMIKACIN SXP 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 SXP 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 30°C.</li></ul>

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

### 6. Are there any side effects?

Common side effects are pain at the injection site, feeling sick, decreased appetite, nausea, headache vomiting 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 SXP

Active ingredient(s): amikacin sulfate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using AMIKACIN SXP. **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 SXP.**

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

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

## 1. Why am I being given AMIKACIN SXP?

**AMIKACIN SXP contains the active ingredient amikacin sulfate.** AMIKACIN SXP is an antibiotic that belongs to a group of medicines called aminoglycosides.

Amikacin SXP works by killing bacteria or preventing their growth.

**AMIKACIN SXP is used to treat serious bacterial infections.**

## 2. What should I know before I am given AMIKACIN SXP?

### Warnings

**You must not be given AMIKACIN SXP if:**

- you are allergic to amikacin sulfate, sulfates of sulfites, 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).

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, sulfites 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 pregnant or planning to become pregnant.

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

You must not be given amikacin if you are breast-feeding.

## 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 SXP and affect how it works.**

These include:

- fluid tablets (furosemide (frusemide), etacrynic acid)
- cisplatin, a medicine used to treat cancer or other platinum compounds
- 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
- bisphosphonates, medicines used to treat loss of bone mass
- indometacin, 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 SXP.**

#### 4. How am I given AMIKACIN SXP?

##### How much you will be given

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

##### How you will be given AMIKACIN SXP

- You will receive AMIKACIN SXP in the hospital.
- AMIKACIN SXP is usually given as an injection into a muscle.
- AMIKACIN SXP can also be given as a slow injection into a vein (intravenously)
- AMIKACIN SXP must only be given by a doctor or a nurse.

##### How long AMIKACIN SXP is given for

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

##### If you are given too much AMIKACIN SXP

As AMIKACIN SXP 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 SXP 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 used too much AMIKACIN SXP, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 SXP?

##### Things you should do

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

##### Things you should not do

- Do not miss any follow-up appointments with your doctor following treatment with AMIKACIN SXP.

##### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how AMIKACIN SXP affects you.**

As with other aminoglycoside medicines, AMIKACIN SXP may cause drowsiness, tiredness or dizziness in some people. Make sure you know how you react to AMIKACIN SXP 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 SXP 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 30°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>loss of vision</li><li>passing less urine than is normal, 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 SXP contains

Each mL of AMIKACIN SXP solution for injection contains amikacin sulfate equivalent to 250 mg (250,000 IU) of amikacin activity.

<b>Active ingredient (main ingredient)</b>	amikacin sulfate
<b>Other ingredients (inactive ingredients)</b>	sodium citrate dihydrate sulfuric acid sodium metabisulfite water for injections
<b>Potential allergens</b>	sodium metabisulfite

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

## What AMIKACIN SXP looks like

AMIKACIN SXP is a sterile, clear, colorless to slightly yellow solution. (AUST R 262734).

## Who distributes AMIKACIN SXP

Southern XP Pty Ltd  
Unit 5/118 Church Street  
Hawthorn VIC 3122  
Australia

### Sponsor:

Southern XP IP Pty Ltd  
Unit 5/118 Church Street  
Hawthorn, 3122, Victoria  
Australia

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