Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AMIKACIN SXP Injection.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking AMIKACIN SXP against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What AMIKACIN SXP is used for

AMIKACIN SXP is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced a-my-noe-GLY-koe-sides). It is used to treat serious bacterial infections

Amikacin works by killing bacteria or preventing their growth.

Your doctor may have prescribed AMIKACIN SXP for another reason.

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

AMIKACIN SXP is available only with a doctor's prescription.

Before you are given AMIKACIN

When you must not be given

You must not be given AMIKACIN SXP if you are allergic to medicines containing amikacin 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.

You must not be given AMIKACIN SXP if you are have experienced serious reactions (such as hearing loss or kidney problems) to amikacin, gentamicin, tobramycin, or neomycin in the past.

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

You must not be given amikacin if you are pregnant or planning to become pregnant. Amikacin may affect your developing baby if you are given it during pregnancy.

Do not take AMIKACIN SXP if you are breastfeeding or planning to breastfeed. It is not known whether amikacin passes into breast milk

If you are not sure whether you should be given AMIKACIN SXP, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if:

- you have had an allergic reaction to any medicine in particular any other antibiotics
- sulphites/sulfates

 any other substances, such as foods, preservatives or dyes

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

- · kidney disease
- · hearing disorders
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease).

Your doctor may want to take special care if you have any of these conditions.

If you have not told your doctor about any of the above, tell them before you are given AMIKACIN SXP.

Taking other medicines

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

Some medicines may be affected by AMIKACIN SXP, or may affect how well it works. These include:

- fluid tablets (frusemide, ethacrynic acid)
- · cisplatin, a medicine used to treat cancer
- some other antibiotics (eg vancomycin, clindamycin, colistin, cephalosporins, penicillins)
- amphotericin, a medicine used to treat some fungal infections
- suxamethonium, a medicine used during surgery to relax muscles
- · some general anaesthetic agents
- opioid analgesics (eg codeine, morphine, pethidine, fentanyl).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking AMIKACIN SXP.

How AMIKACIN SXP is given

How much is given

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

How AMIKACIN SXP is given

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 take too much AMIKACIN SXP (overdose)

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.

In case of overdose, immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26).

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.

While you are being given AMIKACIN SXP

Things you must do

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

Before starting any new medicine, tell your doctor, dentist or pharmacist that you are taking AMIKACIN SXP.

Tell all the doctors, dentists and pharmacists who are treating you 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.

If you become pregnant while being treated with AMIKACIN SXP, tell your doctor immediately.

Things to be careful of

Be careful driving or operating machinery until you know how AMIKACIN SXP affects you.

As with other aminoglycoside medicines, AMIKACIN SXP may 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AMIKACIN SXP.

Like all other medicines, AMISULPRIDE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- · pain at the injection site
- dizziness
- feeling sick
- decreased appetite

- · nausea and vomiting
- fever

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- · hearing problems or ringing in the ears
- · passing less urine than is normal
- numbness, skin tingling, muscle twitching and convulsions
- 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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After being given Amikacin SXP

Storage

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.

Product description

What it looks like

AMIKACIN SXP solution for injection comes in 2mL clear glass ampule containing a clear, colourless to slightly yellow solution.

Ingredients

The active ingredient in AMIKACIN SXP is amikacin sulfate.

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

The solution also contains:

- · sodium citrate
- sulphuric acid
- · sodium metabisulfite
- · water for injection.

The solution for injection does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Southern Cross Pharma Pty Ltd Suite 5/118 Church Street Hawthorn VIC 3122 Australia

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