PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AMIKACIN 500 mg/2 ml PHARMA-Q solution for injection

Amikacin (as amikacin sulphate).

Sugar free

Read all of this leaflet carefully before you are given AMIKACIN 500 mg/2 ml PHARMA-Q.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What AMIKACIN 500 mg/2 ml PHARMA-Q is and what it is used for

AMIKACIN 500 mg/2 ml PHARMA-Q is one of a group of antibiotic medicines called 'aminoglycosides'.

AMIKACIN 500 mg/2 ml PHARMA-Q is used in the treatment of serious infections caused by bacteria sensitive to amikacin.

2. What you need to know before you use AMIKACIN 500 mg/2 ml PHARMA-Q

AMIKACIN 500 mg/2 ml PHARMA-Q should not be administered to you:

- If you have shown signs of hypersensitivity (severe allergy) to amikacin, or other aminoglycoside antibiotics or to any ingredients of AMIKACIN 500 mg/2 ml PHARMA-Q (listed in section 6);
- If you suffer from a disorder called myasthenia gravis (severe weakness of certain muscles of the body);
- If you are pregnant or breastfeeding your baby;
- If you have kidney problems;
- If you have hearing difficulties or tinnitus (ringing or buzzing in the ears).

Warnings and precautions

Special care should be taken with AMIKACIN 500 mg/2 ml PHARMA-Q:

- If you have shown signs of allergy to any of the antibiotics related to amikacin (aminoglycosides) in the past;
- If you have a known allergy to sulphites.

AMIKACIN 500 mg/2 ml PHARMA-Q may lead to changes in your kidney function. Your doctor may take blood and urine samples to monitor for changes such as increased levels of creatinine or nitrogen in the blood and protein or red/white blood cells in urine. Tell your doctor if you have or have had kidney problems before or if you are dehydrated.

AMIKACIN 500 mg/2 ml PHARMA-Q may lead to changes in your hearing and may result in dizziness, vertigo (sensation of spinning), tinnitus (ringing in the ears), roaring in the ears, and

hearing loss. It is extremely important to tell your doctor immediately if you experience any of these symptoms and the hearing loss may be irreversible. Your doctor may also ask you to undergo hearing tests.

AMIKACIN 500 mg/2 ml PHARMA-Q must not be administered to you if you have myasthenia gravis (severe weakness of certain muscles of the body). AMIKACIN 500 mg/2 ml PHARMA-Q should be used with caution in patients with muscular disorders such as Parkinsonism since these medicines may aggravate muscle weakness. AMIKACIN 500 mg/2 ml PHARMA-Q may also cause numbness, skin tingling, muscle twitching and convulsions (seizures).

AMIKACIN 500 mg/2 ml PHARMA-Q may lead to changes in your respiratory system and lead to difficulty breathing.

Children and adolescents

AMIKACIN 500 mg/2 ml PHARMA-Q should be used with caution in premature and new-born babies.

Other medicines and AMIKACIN 500 mg/2 ml PHARMA-Q

Always tell your health care provider if you are taking any other medicine.
(This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Diuretics (water tablets) such as furosemide and ethacrynic acid;
- Other antibiotics that can affect your kidneys, hearing or balance;
- Anaesthetics or muscle-relaxing medicines;
- Indomethacin (an anti-inflammatory medicine);
- Other antibiotics called beta-lactamases such as penicillins or cephalosporins;

- Bisphosphonates (medicines used to treat loss of bone mass);
- Vitamin B1 (thiamine);
- Platinum compounds used in chemotherapy such as cisplatin.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety in pregnancy and breastfeeding has not been established.

Use of AMIKACIN 500 mg/2 ml PHARMA-Q during pregnancy may damage the 8th cranial nerve (sensory nerve) of the unborn baby. AMIKACIN 500 mg/2 ml PHARMA-Q should not be administered to you, if you are pregnant.

It is not known whether amikacin is excreted in human milk. AMIKACIN 500 mg/2 ml PHARMA-Q should not be administered to you if you breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent AMIKACIN 500 mg/2 ml PHARMA-Q may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness,judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which AMIKACIN 500 mg/2 ml PHARMA-Q affects you.

3. How to use AMIKACIN 500 mg/2 ml PHARMA-Q

AMIKACIN 500 mg/2 ml PHARMA-Q is usually injected into a muscle. It may also be given into a vein, either as an injection or (following dilution) as an infusion (drip).
Your doctor will ensure you are well hydrated before and during treatment.
You will not be expected to give yourself AMIKACIN 500 mg/2 ml PHARMA-Q. It will be given to you by a person who is qualified to do so.

Your doctor will work out the correct dose of AMIKACIN 500 mg/2 ml PHARMA-Q for you and how often it must be given. This may require blood tests before treatment.
The dose will depend upon your age, the infection you have, how well your kidneys are working, if you have poor hearing and any other medicines you may be taking.

It will usually be given to you two or three times a day, for up to 10 days.
During treatment you may undergo blood tests and be asked to provide urine samples.
You will possibly also have hearing tests before and during treatment to look for signs of side effects. Your doctor may change your dose depending upon the results of these tests.
If you have the impression that the effect of AMIKACIN 500 mg/2 ml PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you take more AMIKACIN 500 mg/2 ml PHARMA-Q than you should

Since a health care provider will administer AMIKACIN 500 mg/2 ml PHARMA-Q, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take AMIKACIN 500 mg/2 ml PHARMA-Q

Since a health care provider will administer AMIKACIN 500 mg/2 ml PHARMA-Q, it is unlikely that the dose will be missed.

4. Possible side effects

AMIKACIN 500 mg/2 ml PHARMA-Q can have side effects.

Not all side effects reported for AMIKACIN 500 mg/2 ml PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMIKACIN 500 mg/2 ml PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop receiving AMIKACIN 500 mg/2 ml PHARMA-Q and tell your doctor immediately:

- Allergic reactions to AMIKACIN 500 mg/2 ml PHARMA-Q (you may experience a sudden itchy rash (hives), redness, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing);
- Purpura (a rash of purple spots on the skin caused by internal bleeding from small blood vessels).
- Neurotoxicity (numbness, skin tingling, muscle twitching and convulsions); paralysis.
- Bronchospasm constriction of the air passages of the lung causing breathing difficulties
- Toxicity in the kidneys (decrease in the amount of urine you produce or blood in the urine);
- Ringing in your ears or loss of hearing; deafness
- Loss of balance or spinning sensation;
- Blindness or visual disturbances.

These are all very serious side effects. If you have them, you may have had a serious reaction to AMIKACIN 500 mg/2 ml PHARMA-Q. You may need urgent medical attention.

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

- Pseudomembranous colitis (severe diarrhoea which may include blood)
- Unusually low amount of red blood cells in the blood (anaemia) or excessive amounts of the white blood cells known as eosinophils in the blood (eosinophilia);
- Low level of potassium (K) in the blood serum;
- Low levels of magnesium in the blood;
- Low calcium levels in the blood serum;
- Unsteadiness;
- Dizziness;
- Nausea and vomiting;
- Low blood pressure;
- Headache;
- Fever.

These are all serious side effects. You may need urgent medical attention.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of AMIKACIN 500 mg/2 ml PHARMA-Q.

5. How to store AMIKACIN 500 mg/2 ml PHARMA-Q

Store at or below 25°C.

Upon opening of the vial, any unused solution should be discarded. Prepared injections or infusions should be used immediately, however, if this is not possible, they can be stored for up to 24 hours.

KEEP OUT OF REACH OF CHILDREN.

Do not use the medicine after the expiry date on the container.

6. Contents of the pack and other information

What AMIKACIN 500 mg/2 ml PHARMA-Q contains

The active substance is amikacin; each single dose 2 ml vial contains: 500 mg amikacin (as amikacin sulphate).

The other ingredients are sodium meta bisulfite, sodium citrate (dihydrate), sulfuric Acid 10 %, water for Injections.

What AMIKACIN 500 mg/2 ml PHARMA-Q looks like and contents of the pack

2 ml in 2 ml flint glass USP type-I 13 mm neck vial stoppered with 13 mm grey chlorobutyl rubber stopper (RFU) and sealed with 13 mm blue color flip off aluminium seal in a single carton.

Holder of Certificate of Registration

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