APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AMIKACIN 100 mg/2 ml FRESENIUS solution for injection

AMIKACIN 250 mg/2 ml FRESENIUS solution for injection

AMIKACIN 500 mg/2 ml FRESENIUS solution for injection

AMIKACIN 1 g/4 ml FRESENIUS solution for injection

Amikacin

Sugar free

Read all of this leaflet carefully before you receive AMIKACIN FRESENIUS

- 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.
- **AMIKACIN FRESENIUS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AMIKACIN FRESENIUS is and what it is used for

The active ingredient of **AMIKACIN FRESENIUS** is amikacin.

AMIKACIN FRESENIUS belong to a group of antibiotic medicines called ‘aminoglycosides’.

AMIKACIN FRESENIUS is used for treatment of infections caused by hospital acquired organisms that are resistant to other antibiotics.

2. What you need to know before you receive AMIKACIN FRESENIUS

You should not receive AMIKACIN FRESENIUS:

- if you are hypersensitive (allergic) to amikacin or any of the other ingredients of **AMIKACIN FRESENIUS** (listed in section 6).
- if you are pregnant or breastfeeding
- if you have myasthenia gravis (muscle weakness)
- if you have kidney impairment
- if you have a hearing problem

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have a history of allergy to any of the antibiotics related to **AMIKACIN FRESENIUS** (aminoglycosides) in the past
- if you have partial hearing loss or tinnitus (ringing or buzzing in the ears)
- if you have kidney problems
- if you have a known allergy to sulphites
- if you have Parkinson’s disease

- if you or your family members have a mitochondrial mutation disease (a genetic condition) or loss of hearing due to antibiotic medicines, you are advised to inform your doctor or pharmacist before you take an aminoglycoside; certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before administration of **AMIKACIN FRESENIUS**.

Children and adolescents

AMIKACIN FRESENIUS should be used with caution in premature and neonatal infants.

Other medicines and AMIKACIN FRESENIUS

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines as they may interact with **AMIKACIN FRESENIUS**:

- other antibiotics such as other aminoglycosides (e.g., gentamicin, neomycin, streptomycin, tobramycin), cephalosporins, clindamycin, imipenem, polymyxin B, bacitracin, cephaloridine, colistin, paromomycin, penicillin's and vancomycin.
- amphotericin B, a medicine used in the treatment of fungal infections
- diuretics (water tablets) such as furosemide and ethacrynic acid
- medicines called bisphosphonates that are used to treat loss of bone mass
- anti-cancer medicines such as cisplatin
- thiamine (Vitamin B1). If taken with **AMIKACIN FRESENIUS**, it may lose its effectiveness
- anaesthetics such as those used during surgery such as ether, halothane)
- muscle relaxants such as d-tubocurarine, succinyl choline, decamethonium, atracurium, rocuronium, vecuronium
- indomethacin (an anti-inflammatory medicine to reduce fever, pain and joint swelling and stiffness). This can increase the amount of **AMIKACIN FRESENIUS** which is absorbed in

new-born babies.

Pregnancy, breastfeeding and fertility

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 receiving **AMIKACIN FRESENIUS**.

Do not receive **AMIKACIN FRESENIUS** if you are pregnant or breastfeeding.

AMIKACIN FRESENIUS contains sodium metabisulphite

This may rarely cause hypersensitivity (severe allergy) reactions and bronchospasm (breathing difficulties).

AMIKACIN FRESENIUS contains sodium

AMIKACIN 100 mg/2 ml; 250 mg/2 ml; 500 mg/2 ml FRESENIUS and **AMIKACIN 1 g/4 ml FRESENIUS** contains of 2,97 mg; 7,44 mg 15,52 mg and 29,84 mg sodium (main component of cooking/table salt) respectively. This is equivalent to 0,1 %; 0,3 % 0,8 % and 1,5 % respectively of the WHO recommended maximum daily intake of sodium for an adult.

Driving and using machines

It is not always possible to predict to what extent **AMIKACIN FRESENIUS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware to the measure to which **AMIKACIN FRESENIUS** affects them.

3. How to receive AMIKACIN FRESENIUS

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself **AMIKACIN FRESENIUS**. It will be given to you by a person who is qualified to do so.

Dosage:

Your doctor will decide what your dose is and for how long you will receive **AMIKACIN FRESENIUS**.

Your doctor will decide what the correct dose is and for how long you will receive **AMIKACIN FRESENIUS**. For the treatment of infections, the antibiotic is usually given in divided doses throughout the day.

If you have them impression that the effects of **AMIKACIN FRESENIUS** are too strong or too week, tell your doctor or pharmacist.

Method of administration:

You will receive **AMIKACIN FRESENIUS** by infusion into a vein (intravenously) or by injection into a muscle (intramuscularly).

Frequency of administration:

The speed of the infusion and the amount of the solution infused will depend on your specific requirements, the disease for which **AMIKACIN FRESENIUS** is being used, and by reference to the maximum daily dose.

If you received more AMIKACIN FRESENIUS than you should:

Since a health care provider will administer **AMIKACIN FRESENIUS,** he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Missed AMIKACIN FRESENIUS doses

Since a health care provider will administer **AMIKACIN FRESENIUS**, it is unlikely that the dose will be missed. In case of a missed dose, this should not be given on the same day as a scheduled dose.

4. Possible side effects

AMIKACIN FRESENIUS can have side effects.

Not all side effects reported for **AMIKACIN FRESENIUS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **AMIKACIN FRESENIUS**, please consult your doctor, pharmacist, or other health care provider for advice.

If any of the following happens, stop receiving **AMIKACIN FRESENIUS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AMIKACIN FRESENIUS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Unusually low amount of red blood cells (characterised by tiredness, headaches, being short of breath when exercising, dizziness and looking pale);
- Excessive amounts of white blood cells (characterised by infections, fatigue, fever, pain, flu-like symptoms);
- Sudden loss of breathing, difficulty in breathing, wheezing or coughing;
- Loss of hearing (deafness), ringing in your ears or buzzing;

- Problems with kidney function, urinating less than usual;
- Yellowing of your skin and eyes (also called jaundice).

These are serious side effects; you may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects

- Infections with resistant bacteria or yeasts;
- Low levels of magnesium in your blood;
- Low levels of calcium in your blood;
- Low levels of potassium in your blood;
- Shaking or tremors, abnormal tingling or ‘pins and needles’ sensation, headache, dizziness or vertigo (spinning sensation);
- Blindness or other problems with your vision;
- Joint pain, painful, swollen joints, muscle tremors.

Side effects with frequency not known:

- Inability of muscles to move, fits or seizures;
- Nausea (feeling sick), vomiting (being sick);
- Abdominal pain, inflammation of the colon;
- Low blood pressure (characterised by dizziness, light-headedness);
- Hypoventilation (slow and ineffective breathing);
- Acute kidney failure.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the 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 FRESENIUS.**

Health care providers are asked to report any suspected adverse reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store AMIKACIN FRESENIUS

Store all medicines out of reach of children.

AMIKACIN FRESENIUS will be stored in the pharmacy or in the hospital wards.

AMIKACIN FRESENIUS vials are kept in a cool place at a temperature at or below 30 °C, protected from light.

Unused portions of the injection should be discarded.

6. Contents of the pack and other information

What AMIKACIN FRESENIUS contains

The active substance is amikacin.

Each single dose 2 ml vial contains: 100 mg, 250 mg or 500 mg amikacin (as amikacin sulphate).

Each single dose 4 ml solution (in a 5 ml vial) contains: 1 g amikacin (as amikacin sulphate).

The other ingredients are:

Amikacin 100 mg/2 ml Fresenius:

Sodium metabisulphite, sodium citrate dihydrate, sulphuric acid (for pH-adjustment); water for injection.

Amikacin 250 mg/2 ml Fresenius; Amikacin 500 mg/2 ml Fresenius; Amikacin 1 g/4 ml Fresenius:

Sodium metabisulphite, sodium citrate dihydrate, water for injection.

What AMIKACIN FRESENIUS looks like and contents of the pack

AMIKACIN 100 mg/2 ml, 250 mg/2 ml, 500 mg/2 ml FRESENIUS solution for injections are clear, colourless to slightly yellow solutions packed in 2 ml glass vials (Type 1) sealed with rubber stoppers and packed in containers of 10 vials.

AMIKACIN 1 g/4 ml FRESENIUS solution for injection is a clear, colourless to slightly yellow solution packed in 5 ml glass vials (Type 1) sealed with rubber stoppers and packed in containers of 10 vials.

Holder of Certificate of Registration

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AMIKACIN 100 mg/2 ml FRESENIUS: Y/20.1.1/175

AMIKACIN 250 mg/2 ml FRESENIUS: Y/20.1.1/176

AMIKACIN 500 mg/2 ml FRESENIUS: Y/20.1.1/178

AMIKACIN 1 g/4 ml FRESENIUS: : 29/20.1.1/0684

Access to the corresponding Professional Information

To be confirmed.