

## APPROVED PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

### PROPRIETARY NAMES AND DOSAGE FORM

**Amikacin Fresenius 50 mg/2 ml** Injection

**Amikacin Fresenius 100 mg/2 ml** Injection

**Amikacin Fresenius 250 mg/2 ml** Injection

**Amikacin Fresenius 500 mg/2 ml** Injection

**Amikacin Fresenius 1 g/4 ml** Injection

**Read all of this leaflet carefully before you are given Amikacin Fresenius.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **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 AMIKACIN FRESENIUS CONTAINS

The active substance is amikacin.

**Each single dose 2 ml vial contains:**

50 mg, 100 mg, 250 mg or 500 mg amikacin (as amikacin sulphate)

***The other ingredients are:***

Antioxidant: sodium metabisulphite - 0,1 % *m/v*, 0,13 % *m/v*, 0,33 % *m/v* and 0,66 % *m/v* respectively.

Water for injection.

**Each single dose 4 ml solution (in a 5 ml vial) contains:**

1 g amikacin (as amikacin sulphate)

***The other ingredients are:***

Antioxidant: sodium metabisulphite - 0,66 % *m/v*

Water for injection.

**WHAT AMIKACIN FRESENIUS IS USED FOR**

**Amikacin Fresenius** is used for treatment of infections caused by hospital acquired organisms that are resistant to other antibiotics.

**BEFORE YOU RECEIVE AMIKACIN FRESENIUS**

**You should not be given Amikacin Fresenius:**

- if you are sensitive or allergic to amikacin or aminoglycosides or other ingredients of **Amikacin Fresenius**
- if you are pregnant or breastfeeding
- if you have myasthenia gravis (muscle weakness)
- if you have kidney impairment
- if you have a hearing problem

**Take special care with Amikacin Fresenius:**

- if you have a history of allergy
- if you have partial hearing loss

**Pregnancy and breastfeeding:**

Do not receive **Amikacin Fresenius** if you are pregnant or breast feeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or healthcare professional for advice.

**Using other medicines with Amikacin Fresenius:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

**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 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.

**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 have received more Amikacin Fresenius than you should:**

Since a healthcare professional will administer **Amikacin Fresenius** he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**POSSIBLE SIDE EFFECTS**

**Amikacin Fresenius** can have side effects, such as:

- Hypersensitivity reactions (skin itching, redness, rash or swelling)
- Ear disorders (loss of hearing, ringing or buzzing)
- Kidney failure in case of high concentrations of amikacin in the urine and kidney
- Nausea and vomiting

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 healthcare professional for advice.

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

**STORING AND DISPOSING OF AMIKACIN FRESENIUS**

Store all medicines out of reach of children.

**Amikacin Fresenius** will be stored in the pharmacy or in the hospital wards. The injection and vials are kept in a cool place at a temperature at or below 25 °C.

Unused portions of the injection should be discarded.

## **PRESENTATION OF AMIKACIN FRESENIUS**

**Amikacin Fresenius** is packed in containers of 10.

## **IDENTIFICATION OF AMIKACIN FRESENIUS**

**Amikacin Fresenius** is a clear colourless to slightly yellow solution.

## **REGISTRATION NUMBERS**

<b>Amikacin Fresenius 50 mg/2 ml</b>	30/20.1.1/0019
<b>Amikacin Fresenius 100 mg/2 ml</b>	Y/20.1.1/175
<b>Amikacin Fresenius 250 mg/2 ml</b>	Y/20.1.1/176
<b>Amikacin Fresenius 500 mg/2 ml</b>	Y/20.1.1/178
<b>Amikacin Fresenius 1 g/4 ml</b>	29/20.1.1/0684

## **NAME AND ADDRESS OF THE REGISTRATION HOLDER**

Fresenius Kabi Manufacturing SA (Pty) Ltd

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