APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAMES AND DOSAGE FORMS

Gentamycin Fresenius 20 mg/2 ml (vials)

Gentamycin Fresenius 80 mg/2 ml (vials)

Gentamycin Fresenius 20 mg/2 ml (ampoules)

Gentamycin Fresenius 40 mg/1 ml (ampoules)

Gentamycin Fresenius 80 mg/2 ml (ampoules)

Injection

Read the entire leaflet carefully before you are given Gentamycin Fresenius

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Gentamycin Fresenius** has been prescribed for you personally. You should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

1. WHAT GENTAMYCIN FRESENIUS CONTAINS

Gentamycin sulphate equivalent to base 10 mg/ mℓ (in 2 mℓ vials) preserved with methylhydroxybenzoate 0,18 % *m/v* and propylhydroxybenzoate 0,02 % *m/v.*

Gentamycin sulphate equivalent to base 40 mg/mℓ (in 2 mℓ vials) preserved with methylhydroxybenzoate 0,18 % *m/v* and propylhydroxybenzoate 0,02 % *m/v.*

Gentamycin sulphate equivalent to base 10 mg/mℓ (in 2 mℓ ampoules).

Gentamycin sulphate equivalent to base 40 mg/mℓ (in 1 mℓ ampoules).

Gentamycin sulphate equivalent to base 40 mg/mℓ (in 2 mℓ ampoules).

The inactive ingredients are: propylhydroxybenzoate, methylhydroxybenzoate, Water for Injection.

2. WHAT GENTAMYCIN FRESENIUS IS USED FOR

Treatment of infections caused by sensitive organisms.

3. BEFORE YOU ARE GIVEN GENTAMYCIN FRESENIUS

Gentamycin Fresenius should not be administered:

- if you are sensitive or allergic to gentamycin or aminoglycosides or to any of the ingredients of Gentamycin Fresenius
- if you have muscle weakness caused by an illness such as myasthenia gravis or parkinsonism
- if you have a liver problem, hearing problems, or fever

Special care should be taken with Gentamycin Fresenius:

- if you have a history of allergy
- if you have hepatic impairment (liver problems)
- if you have vestibulary (ear/ hearing) problems. Exposure to loud noise may increase the risk of Gentamycin Fresenius causing problems with your hearing
- if you have kidney problems.

Take special care if you are a female or if you have low blood pressure, are dehydrated or have a liver problems, as you may be at a higher risk of kidney problems with Gentamycin Fresenius.

Pregnancy and breastfeeding

Do not use Gentamycin Fresenius if you pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice as you should not receive Gentamycin Fresenius.

Taking other medicines with Gentamycin Fresenius

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

Tell your doctor if you are using diuretics (water tablets), another aminoglycoside, or cephalosporins (antibiotics), before receiving Gentamycin Fresenius.

4. HOW TO RECEIVE GENTAMYCIN FRESENIUS

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

You will not be expected to give yourself Gentamycin Fresenius. It will be administered 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 be receiving this medicine. For the treatment of infections, the antibiotic is usually given in divided doses throughout the day.

Method of administration:

You will receive this medicine by injection into a muscle (intramuscularly) or in special cases by infusion into a vein (intravenously). The speed of the infusion and the amount of the solution infused will depend on your specific requirements, the disease for which the product is being used, and by reference to the maximum daily dose.

If you have received more Gentamycin Fresenius than you should

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

5. POSSIBLE SIDE EFFECTS

Gentamycin Fresenius can have side effects such as:

- Hypersensitivity reactions (allergic reactions)
- Ear disorders (hearing disorder)
- Kidney disorders
- Allergic reactions which includes a flaking or rash of the skin
- Nausea and vomiting

Not all side effects reported for Gentamycin Fresenius are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Gentamycin 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.

6. STORING AND DISPOSING OF GENTAMYCIN FRESENIUS

Store all medicines out of reach of children.

Gentamycin Fresenius will be stored in pharmacy or in the hospital wards. The injection and vials are kept in cool dry place at a temperature at or below 30 °C. Unused portions of the injection should be discarded.

7. PRESENTATION OF GENTAMYCIN FRESENIUS

2 ml vials of 10 mg/ml (pack of 10 units)

2 ml vials of 40 mg/ml (pack of 10 units)

2 ml ampoules of 10 mg/ml (pack of 10 units)

1 ml ampoules of 40 mg/ ml (pack of 10 units)

2 ml ampoules of 40 mg/ml (pack of 10 units)

8. IDENTIFICATION OF GENTAMYCIN FRESENIUS

A clear, colourless glass ampoule or vial containing a clear colourless to slightly yellow solution.

9. REGISTRATION NUMBER

Gentamycin Fresenius 20 mg/2 ml (vials)	N/20.1.1/71
Gentamycin Fresenius 80 mg/2 ml (vials)	L/20.1.1/165
Gentamycin Fresenius 20 mg/2 ml (ampoules)	L/20.1.1/162
Gentamycin Fresenius 40 mg/1 ml (ampoules)	L/20.1.1/163
Gentamycin Fresenius 80 mg/2 ml (ampoules)	L/20.1.1/164

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Fresenius Kabi Manufacturing SA (Pty) Ltd

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11. DATE OF PUBLICATION

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