

# Approved Patient information Leaflet for TOBRAMYCIN 80 mg/2 ml FRESENIUS

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**    **S4**

**TOBRAMYCIN 80 mg/2 ml FRESENIUS solution for injection or infusion**

**Tobramycin**

**Sugar free.**

**Read all of this leaflet carefully before you are given TOBRAMYCIN 80 mg/2 ml FRESENIUS**

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

### **What is in this leaflet**

1. What TOBRAMYCIN 80 mg/2 ml FRESENIUS is and what it is used for
2. What you need to know before you are given TOBRAMYCIN 80 mg/2 ml FRESENIUS
3. How to receive TOBRAMYCIN 80 mg/2 ml FRESENIUS
4. Possible side effects
5. How to store TOBRAMYCIN 80 mg/2 ml FRESENIUS
6. Contents of the pack and other information.

## **1. What TOBRAMYCIN 80 mg/2 ml FRESENIUS is and what it is used for**

TOBRAMYCIN 80 mg/2 ml FRESENIUS belongs to a group of medicines called broad and medium spectrum antibiotics.

TOBRAMYCIN 80 mg/2 ml FRESENIUS is used for the treatment of severe infections such as urinary tract infections, respiratory tract infections and infections that you could get while being in hospital.

## **2. What you need to know before you are given TOBRAMYCIN 80 mg /2 ml FRESENIUS**

### **You should not be administered TOBRAMYCIN 80 mg/2 ml FRESENIUS:**

- if you are sensitive or allergic to tobramycin, other aminoglycosides, or any of the ingredients of TOBRAMYCIN 80 mg/2 ml FRESENIUS (listed in section 6)
- if you are pregnant or breastfeeding your baby
- if you have any muscle disorder such as myasthenia gravis or parkinsonism.

### **Warnings and precautions**

Take special care with TOBRAMYCIN 80 mg/2 ml FRESENIUS:

- if you are asthmatic or have ever had an allergic reaction to a sulphate or bisulphite (preservatives)
- if you or your family members have a mitochondrial mutation disease (condition caused by variants in the genome of mitochondria, the parts of your cells which help make energy) or loss of hearing due to antibiotics, certain mitochondrial mutations may increase your risk of hearing loss with TOBRAMYCIN 80 mg/2 ml FRESENIUS
- if you have a kidney disorder or need dialysis (you may need a reduced dose, especially if you are an elderly patient)

- if you have hepatic impairment (liver problems) or vestibular (ear/auditory) problems
- if you are obese
- if you have cystic fibrosis (a lung disease)
- if you have a high temperature or hypotension (low blood pressure)
- if you have extensive burns
- if you are receiving large volume transfusions of citrated blood.

## **Children**

TOBRAMYCIN 80 mg/2 ml FRESENIUS should be used with caution in premature and neonatal infants.

## **Other medicines and TOBRAMYCIN 80 mg/2 ml FRESENIUS:**

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

The following medicines may cause an interaction with TOBRAMYCIN 80 mg/2 ml FRESENIUS and should not be used together:

- succinylcholine, tubocurarine or decamethonium (used in the relaxation of skeletal muscles)
- penicillins or cephalosporins (used to treat certain bacterial infections)
- other aminoglycosides (similar antibiotics such as amikacin, streptomycin, neomycin, kanamycin, gentamicin or paromomycin), other antibiotics (such as amphotericin B, cefaloridine, viomycin, polymyxin B, colistin, vancomycin) and cephalosporin antibiotics (such as cephalothin) (used to treat certain bacterial infections)
- pyridostigmine or neostigmine (used to treat myasthenia gravis, a muscle disorder)
- diuretics (water tablets) (used to treat high blood pressure)

- ciclosporin (used to suppress the activity of the immune system)
- cisplatin (used as chemotherapy to treat cancer)
- warfarin and phenindione (used to prevent the forming of blood clots).

### **Pregnancy and breastfeeding**

Do not receive TOBRAMYCIN 80 mg/2 ml FRESENIUS if you are pregnant or breastfeeding. TOBRAMYCIN 80 mg/2 ml FRESENIUS may harm your unborn baby.

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 TOBRAMYCIN 80 mg/2 ml FRESENIUS.

### **Driving and using machines**

TOBRAMYCIN 80 mg/2 ml FRESENIUS may cause dizziness and vertigo (spinning sensation) which may affect your ability to drive a vehicle or operate machines. Take special care when performing tasks that require your attention, until you know how TOBRAMYCIN 80 mg/2 ml FRESENIUS will affect you.

### **TOBRAMYCIN 80 mg/2 ml FRESENIUS contains sodium metabisulphite and sodium**

TOBRAMYCIN 80 mg/2 ml FRESENIUS contains sodium metabisulphite as preservative and may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty in breathing). TOBRAMYCIN 80 mg/2 ml FRESENIUS contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially sodium free.

### **3. How to receive TOBRAMYCIN 80 mg/2 ml FRESENIUS**

You will not be expected to give yourself TOBRAMYCIN 80 mg/2 ml 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 be receiving TOBRAMYCIN 80 mg/2 ml FRESENIUS. For the treatment of infections, TOBRAMYCIN 80 mg/2 ml FRESENIUS is usually given in divided doses throughout the day.

#### **Method of administration:**

You will receive TOBRAMYCIN 80 mg/2 ml FRESENIUS by injection into a vein (intravenously) or by injection into a muscle (intramuscularly). The rate of the injection and the amount of the solution injected will depend on your specific requirement, the disease for which TOBRAMYCIN 80 mg/2 ml FRESENIUS is being used and with reference to the maximum daily dose.

#### **If you have received more TOBRAMYCIN 80 mg/2 ml FRESENIUS than you should**

Since a health care provider will administer TOBRAMYCIN 80 mg/2 ml FRESENIUS, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

### **4. Possible side effects**

TOBRAMYCIN 80 mg/2 ml FRESENIUS can have side effects.

Not all side effects reported for TOBRAMYCIN 80 mg/2 ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving

TOBRAMYCIN 80 mg/2 ml FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving TOBRAMYCIN 80 mg/2 ml FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and 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 reaction to TOBRAMYCIN 80 mg/2 ml FRESENIUS. You may need urgent medical attention.

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

*Frequently occurring side effects*

- Damage to your nerves (numbness, pins and needles, muscle twitching).
- Seizure/convulsions.
- Ear disorder (ototoxicity) – poisoning of the ear affecting the function of the ear.
- Kidney disorder (nephrotoxicity) – poisoning of the kidney affecting the functioning of the kidney, leading to less urine than is normal for you.

*Less frequently occurring side effects*

- Difficulty breathing, muscular weakness.

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

Tell your doctor as soon as possible if you notice any of the following:

### *Frequently occurring side effects*

- Spinning sensation (vertigo), ringing, buzzing or roaring noise in your ears (tinnitus), hearing loss.

### *Side effects occurring with an unknown frequency*

- Blood disorders characterised by unusual weakness or tiredness, fever, infections, abnormal bleeding or easy bruising.
- Encephalopathy (a brain disease, leading to an altered mental state), mental confusion, abnormal drowsiness, seeing or hearing things that do not exist (hallucinations), disorientation.
- Meningeal irritation (neck stiffness), arachnoiditis (numbness or tingling in the legs).
- Visual disorders.
- Pseudomembranous colitis (watery and/or bloody diarrhoea), nausea (feeling sick), vomiting (being sick), fever.
- Abnormal liver and kidney function (as determined by blood tests).
- Low levels of magnesium, calcium, sodium or potassium.

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 **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 TOBRAMYCIN 80 mg/2 ml FRESENIUS.

Health care providers are asked to report any suspected Adverse Drug Reactions to the Holder of the Certificate of Registration at the following email address: [safety.fksa@fresenius-kabi.com](mailto:safety.fksa@fresenius-kabi.com), and

to the relevant medicine's regulatory authority in the country where the product is marketed.

## **5. How to store TOBRAMYCIN 80 mg/2 ml FRESENIUS**

Store all medicines out of reach of children.

TOBRAMYCIN 80 mg/2 ml FRESENIUS will be stored in the pharmacy or in the hospital wards.

The vials are kept at or below 25 °C.

Unused portions of the injection should be discarded.

## **6. Contents of the pack and other information**

### **What TOBRAMYCIN 80 mg/2 ml FRESENIUS contains:**

The active substance in each ml is 40 mg tobramycin as the sulphate.

The other ingredients are benzyl alcohol 0,9 % *v/v* (preservative), disodium edetate, sodium metabisulphite 0,32 % *m/v* (antioxidant), sulphuric acid 10 % (for pH-adjustment) and water for injection.

Sugar free.

### **What TOBRAMYCIN 80 mg/2 ml FRESENIUS looks like and contents of the pack:**

A clear, colourless solution in 2 ml clear glass vials (Type I) sealed with bromobutyl rubber stoppers, in cartons of 10 vials.

### **Holder of Certificate of Registration and Manufacturer:**

Fresenius Kabi Manufacturing SA (Pty) Ltd

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