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**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:****S4****LINEZOLID 600 mg/300 mL FRESENIUS solution for infusion****Linezolid****Contains sugar: Glucose monohydrate 15,072 g****Read all of this leaflet carefully before you are given LINEZOLID 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.

**What is in this leaflet**

1. What LINEZOLID FRESENIUS is and what it is used for
2. What you need to know before you are given LINEZOLID FRESENIUS
3. How LINEZOLID FRESENIUS will be administered to you
4. Possible side effects
5. How to store LINEZOLID FRESENIUS
6. Contents of the pack and other information

**1. What LINEZOLID FRESENIUS is and what it is used for**

The active ingredient, linezolid, is an antibiotic of the so-called oxazolidinones group. It acts by stopping the growth of certain bacteria (germs) that cause infections.

LINEZOLID FRESENIUS is used by your doctor to treat pneumonia and manage some infections in the skin or under the skin. Your doctor will decide if LINEZOLID FRESENIUS is suitable to be used for the type of infection you have.

## **2. What you need to know before you are given LINEZOLID FRESENIUS**

### **LINEZOLID FRESENIUS should not be administered to you:**

- if you are hypersensitive (allergic) to linezolid or any of the other ingredients of LINEZOLID FRESENIUS (listed in section 6).
- if you are treated with monoamine oxidase inhibitors (examples of MAOIs are phenelzine, selegiline, moclobemide) or within 2 weeks of taking such a medicine. These medicines may be used to treat depression or Parkinson's disease.
- if you breastfeed your baby.

### **Warnings and precautions**

#### **Tell your doctor or health care provider before being given LINEZOLID FRESENIUS injection:**

- if you have high blood pressure and what medicines you are taking for this (see section 2, "Other medicines and LINEZOLID FRESENIUS");
- if you have been diagnosed with an overactive thyroid gland (symptoms may be increased appetite, weight loss or sweating);
- if you have a tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing);
- if you suffer from manic depression, schizoaffective disorder (a mental condition that causes both a loss of contact with reality and mood problems), mental confusion or other mental problems;

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- if you have recurrent nausea or vomiting, abdominal pain or over breathing (a condition known as lactic acidosis, it is when lactic acid builds up in the bloodstream faster than it can be removed and can be life-threatening);
  - if you have been diagnosed with anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness);
  - if you bruise and bleed easily;
  - if you get infections easily;
  - if you have a history of seizures (“fits”) or if you experienced agitation, confusion, coma, stiff muscles, trembling, poor coordination and fits while also taking antidepressants known as SSRIs;
  - if you have liver or kidney problems (especially if you have dialysis);
  - if you have diarrhoea (see section 4);
  - if you take or are given any medicines for cold and flu, asthma, depression, migraine, sudden severe allergic reactions, blood pressure, severe pain, anxiety, other infections. See section 2 “Other medicines and LINEZOLID FRESENIUS” for more information;
  - if you have porphyria (a rare inherited blood disease).

***You should also know that:***

- LINEZOLID FRESENIUS may cause serious diarrhoea and infection in the bowels (see section 4). You may develop diarrhoea while taking, or after taking antibiotics, including LINEZOLID FRESENIUS. If this becomes severe or persistent or you notice that your stool contains blood or mucus, treatment with LINEZOLID FRESENIUS should be stopped immediately and your doctor consulted. In this situation, you should not take medicines that stop or slow bowel movement.
- LINEZOLID FRESENIUS may cause vision problems (see section 4). Tell your doctor immediately if you have problems with your vision such as blurred vision,

changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

- Lactic acidosis: Tell your doctor if you have muscle aches, burning, rapid breathing, nausea, stomach pain. See section 4 for more information on side effects.
- If you are an elderly person, you are at a greater risk of developing blood disorders such as anaemia, lower white cell counts, and lower platelet counts. As you will be in hospital, regular blood tests may help reveal blood disorders.

### **Other medicines and LINEZOLID FRESENIUS**

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

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the medicines listed below.

- You must **not receive** LINEZOLID FRESENIUS if you are currently taking or have taken within the last 14 days MAOIs (for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease. See "LINEZOLID FRESENIUS should not be administered to you".
- Your doctor may consider using another medicine if you currently take/use or have recently used the following medicines:
  - Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
  - Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
  - Medicines used to treat migraine such as sumatriptan and zolmitriptan.
  - Medicines used to treat sudden, severe allergic reactions such as epinephrine (adrenaline).

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- Medicines which increase your blood pressure, such as norepinephrine (noradrenaline), dopamine and dobutamine.
  - Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors), for example amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine and sertraline.
  - Medicines used to treat anxiety disorders, such as buspirone.
  - Medicines used to treat moderate to severe pain, such as pethidine.
  - Medicines that stop blood clotting, such as warfarin.
  - An antibiotic for TB called rifampicin.

### **LINEZOLID FRESENIUS with food, drink and alcohol**

Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g. soy sauce and drinking alcohol, especially draught beers and wine. This is because this medicine may react with a substance called tyramine which is naturally present in some foods and so cause an increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

### **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 you receive LINEZOLID FRESENIUS.**

The effect of LINEZOLID FRESENIUS in pregnant women is unknown; it should therefore not be used during pregnancy.

You should not breastfeed your baby while receiving LINEZOLID FRESENIUS because it passes into breast milk and could affect the baby.

### **Driving and using machines**

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LINEZOLID FRESENIUS may make you feel dizzy or experience problems with your vision (see section 4). Do not drive or use tools or machines if this happens, as LINEZOLID FRESENIUS could interfere with your ability to drive safely.

It is not always possible to predict to what extent LINEZOLID 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 of the measure to which LINEZOLID FRESENIUS affects them.

### **LINEZOLID FRESENIUS contains sugar (glucose) and sodium**

#### ***Glucose***

LINEZOLID FRESENIUS contains 15,072 g glucose monohydrate per 300 mL solution. Please tell your doctor or nurse if you are diabetic or if you have glucose intolerance.

#### ***Sodium***

LINEZOLID FRESENIUS also contains 131 mg sodium (as sodium citrate) per 300 mL solution. Please tell your doctor or nurse if you are on a low sodium diet.

### **3. How LINEZOLID FRESENIUS will be administered to you**

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

LINEZOLID FRESENIUS is normally administered in hospital and will be infused (dripped) into a large vein.

Your doctor will tell you how long your treatment with LINEZOLID FRESENIUS will last.

Do not stop treatment early, since a full course of antibiotic treatment is necessary to kill the germs that made you ill (see below under “If you stop receiving LINEZOLID FRESENIUS”).

If you have the impression that the effect of LINEZOLID FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

**If you receive more LINEZOLID FRESENIUS than you should**

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

Tell your doctor or health care provider at once if you think you may have been given too much LINEZOLID FRESENIUS.

**If you forget to receive LINEZOLID FRESENIUS**

You need not remember when to get your next dose; you will be cared for in hospital/clinic by a professional health care provider, who will ensure that you receive the correct amount of LINEZOLID FRESENIUS at the right time.

If you think you have missed a dose please ask your doctor or health care provider.

Do not receive a double dose to make up for forgotten individual doses.

**If you stop receiving LINEZOLID FRESENIUS**

To clear up your infection completely, LINEZOLID FRESENIUS should be used for the full course of treatment as prescribed by your doctor.

Your symptoms may improve before the infection is completely treated. Stopping early may have the effect that the germs causing the infection become resistant to LINEZOLID FRESENIUS.

**4. Possible side effects**

LINEZOLID FRESENIUS can have side effects.

**Not all side effects reported for LINEZOLID FRESENIUS are included in this leaflet.**

**Should your general health worsen or if you experience any untoward effects while receiving LINEZOLID FRESENIUS, please consult your health care provider for advice.**

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**Your medical condition will also be carefully monitored in a hospital or clinic.**

**Your doctor/nurse will notice if you get any of the following very serious side effects (frequency unknown):**

- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), or bacterial infection of the bowels, which in rare circumstances may develop into complications that are life-threatening.
- Serious allergic reactions, including a shock reaction. You may have swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with very fast heartbeat and heavy sweating.
- Skin reactions such as hives (nettle rash), red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be a sign of a severe allergic reaction and it may be necessary that treatment with LINEZOLID FRESENIUS be stopped.
- Lactic acidosis (signs may be recurrent nausea or vomiting, abdominal pain or over breathing). Lactic acidosis exists when lactic acid builds up in the bloodstream faster than it can be removed and can be life-threatening.
- Fits or seizures (see “Tell your doctor or health care provider before being given LINEZOLID FRESENIUS injection”).
- Serotonin syndrome (which is an excessive accumulation of serotonin in your body and causes symptoms like fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering). Serotonin syndrome is a very serious condition which may occur when two medicines that affect the body's level of serotonin are administered together at the same time. See section 2 “Other medicines and LINEZOLID FRESENIUS”.
- Problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

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- Transient ischaemic attacks (“mini-stroke” with signs like temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness).

Your doctor will stop giving you LINEZOLID FRESENIUS and you will be given urgent medical attention.

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

***Side effects occurring frequently:***

- Fungal infections, especially vaginal or oral “thrush”.
- Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia.
- Headache.
- Metallic taste in the mouth.
- Nausea (feeling sick), vomiting (being sick), abdominal pains, diarrhoea (loose bowels).
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels.

***Side effects occurring less frequently***

- Inflammation of the vagina or genital area in women.
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection.
- Difficulty in sleeping.
- Dizziness, sensations such as tingling or numbness of fingers and toes.
- Convulsions (“fits”).
- Blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

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- “Ringing” in the ears (tinnitus).
  - Changes in heart rate (e.g., increased rate).
  - Increased blood pressure (your doctor will test your blood pressure) inflammation of the veins.
  - Indigestion, stomach pain, constipation, distended belly, thirst, loose stools.
  - Dry or sore mouth, swollen, sore, or discoloured tongue.
  - Hair loss, sweating, itching.
  - Superficial tooth discolouration.
  - Kidney failure, excessive or abnormally large production or passage of urine.

**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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LINEZOLID FRESENIUS.

You may report any suspected adverse drug reactions to your healthcare provider or the Holder of the Certificate of Registration at the following email address:

safety.fksa@fresenius-kabi.com and to the relevant medicine’s regulatory authority in the country where the LINEZOLID FRESENIUS is marketed.

### **5. How to store LINEZOLID FRESENIUS**

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Store at room temperature, at or below 25 °C. Do not freeze. Protect from light – the infusion bags must be kept in their overpouch, until ready to use. The infusion bags and KabiPac bottles are only intended for single use. Discard any unused solution.

**KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.**

Your health care provider will check that the LINEZOLID FRESENIUS is not past its expiry date stated on the label and carton before giving you the injection.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). Return all unused medicine to your pharmacist.

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

### **What LINEZOLID FRESENIUS contains**

**The active substance** is linezolid.

Each 300 mL infusion bag or bottle of LINEZOLID FRESENIUS contains 600 mg linezolid: providing 2 mg linezolid per mL.

**The other ingredients are** water for injections, glucose monohydrate, sodium citrate, citric acid (anhydrous), hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

Contains sugar: Glucose monohydrate 15,072 g.

### **What LINEZOLID FRESENIUS looks like and contents of the pack**

A ready-to-use infusion bag or unit dose KabiPac bottles containing a clear, colourless to yellow solution, free of visible particles.

#### **FreeFlex bags**

Single use freeflex infusion bags packaged in an aluminium foil overpouch, available in a pack size of 300 mL (600 mg linezolid).

The freeflex® container closure system for LINEZOLID FRESENIUS solution for infusion consists of three components: film, ports (tubes and closure system consisting of

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stoppers and caps) and hot stamp foil ink. A printed overwrap provides additional product protection from loss of water (via permeation) as well as protection from light.

**KabiPac bottles**

300 mL solution is filled into a 500 mL KabiPac bottle. The KabiPac packaging system consists of a polyethylene bottle and a cap with an administration point and an addition point, which are two separate, easily distinguishable ports for infusion and injection. The cap is made of polyethylene or a mixture of polyethylene and polypropylene.

Inside the cap, two polyisoprene stoppers serve for the insertion and support of the needle or the spike. The KabiPac packaging system is a unit dose container with a hanger at the bottom of the bottle.

The KabiPac bottles are packed individually into cartons. Ten such single-packed bottles are then packed into an outer carton in pack sizes of 10 x 300 mL.

**Holder of Certificate of Registration**

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**This leaflet was last revised on**

23 July 2024

**Registration Number**

48/20.1.1/0434

**Access to the corresponding Professional Information**

The corresponding Professional Information (PI) can be accessed at

[https://www.fresenius-kabi.com/za/fresenius\\_kabi\\_south\\_africa\\_products](https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products)