

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrZYVOXAM®

#### linezolid injection

Read this carefully before you start taking **ZYVOXAM** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZYVOXAM**.

#### What is ZYVOXAM used for?

**ZYVOXAM** is an antibiotic medicine. It is used to treat the following bacterial infections in adults:

- abdomen infections
- skin infections
- infections of system that carries urine out of body (urinary tract)
- lung infections (pneumonia)

Antibacterial drugs like **ZYVOXAM** treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, **ZYVOXAM** should be used exactly as directed. Misuse or overuse of **ZYVOXAM** could lead to the growth of bacteria that will not be killed by **ZYVOXAM** (resistance). This means that **ZYVOXAM** may not work for you in the future. Do not share your medicine.

#### How does ZYVOXAM work?

**ZYVOXAM** belongs to the class of medicines called oxazolidinones antibiotics. It works by stopping the growth of bacteria responsible for your infection.

#### What are the ingredients in ZYVOXAM?

Medicinal ingredient: Linezolid

Non-medicinal ingredients: citric acid, dextrose, hydrochloric acid (pH adjustment), sodium citrate, sodium hydroxide (pH adjustment) and water for injection.

#### ZYVOXAM comes in the following dosage forms:

**ZYVOXAM** comes as a liquid to give as a shot slowly into a vein.

**ZYVOXAM** is supplied as a 300 mL single-dose infusion bag.

Each 300 mL infusion bag of **ZYVOXAM** contains 600 mg of linezolid.

#### Do not use ZYVOXAM if you:

- are allergic to linezolid or any other ingredients of **ZYVOXAM** (see **What are the ingredients in ZYVOXAM?**).
- have uncontrolled high blood pressure
- have pheochromocytoma [a tumor of small part of the body, located on top of each kidney (adrenal gland)]
- have thyrotoxicosis (an overactive thyroid)

- have carcinoid syndrome (a condition caused by tumours of the hormone system with signs of diarrhea, skin flushing, rapid heartbeat, wheezing)
- are taking any of the medications listed in the Serious Drug Interactions box below.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZYVOXAM. Talk about any health conditions or problems you may have, including if you:**

- have a history of high blood pressure.
- have taken a drug for low mood (depression) within the last 2 weeks (14 days).
- are taking diuretics (water pills).
- have a history of anemia (low red blood cells), thrombocytopenia [(low cells in the blood that help the blood clot (platelets)], neutropenia (low white blood cells) or any other blood related problems.
- have liver problems
- have kidney problems
- have a history of bleeding problems.
- have a history of seizures or convulsions.
- have diabetes. You will need to watch your blood sugar closely.
- are pregnant or trying to become pregnant.
- are breast-feeding. ZYVOXAM passes in breast milk. Your healthcare professional may advise you to monitor your baby for diarrhea or vomiting while being breastfed.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### Serious Drug Interactions

Do not take ZYVOXAM if you:

- have taken certain medications used for low mood (depression) like isocarboxazid, phenelzine or tranylcypromine or medications used for Parkinson's disease like selegiline or rasagiline in the last 14 days
- are taking any cold or flu medication containing pseudoephedrine or phenylpropanolamine\*
- are taking epinephrine, a medication used for severe allergic reactions
- are taking any other medication that increases blood pressure like norepinephrine, dopamine or dobutamine
- are taking any medication known as selective serotonin re-uptake inhibitors (SSRI's)-(e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) or serotonin norepinephrine reuptake inhibitors (SNRIs) (e.g., desvenlafaxine, duloxetine, venlafaxine). These medications may be used for low mood (depression).
- are taking tricyclic antidepressants, medications for low mood such as amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline
- are taking medications for migraine such as almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- are taking meperidine or other opioid, medications for pain
- are taking buspirone, a medication for anxiety

\* phenylpropanolamine is no longer marketed in Canada

### The following may interact with ZYVOXAM:

- Tyramine, a chemical naturally present in some pickled, smoked, or fermented foods or drinks like aged cheese and red wines. This interaction may cause a sudden increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your healthcare professional. To prevent these problems, get a list of tyramine-rich foods to avoid from your healthcare professional while taking **ZYVOXAM**.

### How to take ZYVOXAM:

- Follow your doctor's instructions carefully.
- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better. **ZYVOXAM** is not normally used in children and teenagers under 18 years old.
- If you develop severe diarrhea during or over 2 months after treatment with **ZYVOXAM**, call your healthcare professional immediately (see What are possible side effects from using **ZYVOXAM**? section below).
- Do not use any medicine to treat your diarrhea without first checking with your doctor.
- Your healthcare professional will give **ZYVOXAM** (injection) by intravenous infusion (slow drip through a needle (into a large vein) over a period of 30 to 120 minutes.

### Usual dose:

(Adults, 18 years and older): 600 mg twice a day (every 12 hours) for 10 to 28 days.

Your healthcare professional will tell you how long you need to take **ZYVOXAM** (injection).

### Overdose:

If you think you, or a person you are caring for, have taken too much **ZYVOXAM**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### What are possible side effects from using ZYVOXAM?

These are not all the possible side effects you may have when taking **ZYVOXAM**. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Headache
- Diarrhea
- Nausea
- Vomiting
- Dizziness
- Change in taste
- Fungal infection
  - white patches in mouth, tongue or throat (oral thrush)

- for women, vaginal yeast infection with itching and irritation in the vagina, pain or burning when urinating (peeing), vaginal discharge
- Tongue discoloration
- Fever
- Insomnia
- Constipation
- Rash
- Dry mouth
- Stomach discomfort
- Increased thirst
- High blood sugar (blurred vision, unusual thirst, increased frequency and amount of urination, a fruit-like breath odor, rapid breathing)
- Low blood sugar (dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating)
- Ringing in the ear
- High blood pressure (watch your blood pressure closely)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<u>UNCOMMON</u> <b>Blood problems</b> (decrease in the level of blood cells): Unusual bleeding or bruising, feeling very tired or weak shortness of breath, fever and chills, sore throat		√	
<b>Vision problems:</b> blurred vision, changes in colour vision, loss of vision		√	
Numbness, tingling, prickling sensations or burning pain		√	
<b>Signs of too much lactic acid in the blood</b> (lactic acidosis): feeling very tired or weak, feeling cold, severe nausea with or without vomiting, stomach pain, fast breathing, fast heartbeat, a heartbeat that does			√

not feel normal, muscle pain or cramps			
<b>Allergic reactions:</b> rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing; swelling of the mouth, face, lips, tongue, or throat			√
<b>Clostridium difficile colitis</b> (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
<b>Serotonin syndrome</b> (occur within several hours of starting a new medicine or increasing the dose of a drug you are already taking): severe headache, agitation, fever, fast heartbeat, flushing, seizures, shakiness, sweating a lot, change in balance, change in thinking clearly, severe upset stomach and throwing up, severe loose stools			√
<b>Severe Cutaneous Adverse Reactions (SCAR):</b> severe skin reactions that may also affect other organs:  <ul style="list-style-type: none"> <li>• Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish)</li> <li>• Swelling and redness of eyes or face</li> <li>• Flu-like feeling, fever, chills, body aches, swollen glands, cough</li> <li>• Shortness of breath, chest pain or discomfort</li> </ul>			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

The healthcare professional will store the product under appropriate conditions.

Keep out of reach and sight of children.

### **If you want more information about ZYVOXAM:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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Pr **ZYVOXAM**<sup>®</sup>

#### linezolid powder for oral suspension

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#### How does **ZYVOXAM** work?

**ZYVOXAM** belongs to the class of medicines called oxazolidinones antibiotics. It works by stopping the growth of bacteria responsible for your infection.

#### What are the ingredients in **ZYVOXAM**?

Medicinal ingredient: Linezolid

Non-medicinal ingredients: aspartame, carboxymethylcellulose sodium, citric acid, colloidal silicon dioxide, mannitol, microcrystalline cellulose, orange flavour, sodium benzoate, sodium chloride, sodium citrate, sucrose and xanthan gum.

#### **ZYVOXAM** comes in the following dosage forms:

**ZYVOXAM** is supplied as an orange-flavored granule/powder for oral suspension (liquid to take by mouth).

Your healthcare professional will mix the powder with water before use.

Once mixed with water, each 5 mL of **ZYVOXAM** Oral Suspension contains 100 mg of linezolid.

**Do not use ZYVOXAM if you:**

- are allergic to linezolid or any other ingredients of **ZYVOXAM** (see **What are the ingredients in ZYVOXAM?**).
- have uncontrolled high blood pressure
- have pheochromocytoma [a tumor of small part of the body, located on top of each kidney (adrenal gland)]
- have thyrotoxicosis (an overactive thyroid)
- have carcinoid syndrome (a condition caused by tumours of the hormone system with signs of diarrhea, skin flushing, rapid heartbeat, wheezing)
- are taking any of the medications listed in the Serious Drug Interactions box below.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZYVOXAM. Talk about any health conditions or problems you may have, including if you:**

- have a history of high blood pressure.
- have taken a drug for low mood (depression) within the last 2 weeks (14 days).
- are taking diuretics (water pills).
- have a history of anemia (low red blood cells), thrombocytopenia [(low cells in the blood that help the blood clot (platelets))], neutropenia (low white blood cells) or any other blood related problems.
- have liver problems
- have kidney problems
- have a history of bleeding problems.
- have a history of seizures or convulsions.
- have diabetes. You will need to watch your blood sugar closely.
- are pregnant or trying to become pregnant.
- are breast-feeding. ZYVOXAM passes in breast milk. Your healthcare professional may advise you to monitor your baby for diarrhea or vomiting while being breastfed.
- have a condition called phenylketonuria (PKU).

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### Serious Drug Interactions

Do not take ZYVOXAM if you:

- have taken certain medications used for low mood (depression) like isocarboxazid, phenelzine or tranylcypromine or medications used for Parkinson's disease like selegiline or rasagiline in the last 14 days
- are taking any cold or flu medication containing pseudoephedrine or phenylpropanolamine\*
- are taking epinephrine, a medication used for severe allergic reactions
- are taking any other medication that increases blood pressure like norepinephrine, dopamine or dobutamine
- are taking any medication known as selective serotonin re-uptake inhibitors (SSRI's)-(e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) or serotonin norepinephrine reuptake inhibitors (SNRIs) (e.g., desvenlafaxine, duloxetine, venlafaxine). These medications may be used for low mood (depression).
- are taking tricyclic antidepressants, medications for low mood such as amitriptyline, clomipramine, desipramine, doxepin, imipramine, nortriptyline
- are taking medications for migraine such as almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan
- are taking meperidine or other opioid, medications for pain
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- Tyramine, a chemical naturally present in some pickled, smoked, or fermented foods or drinks like aged cheeses or red wines. This interaction may cause a sudden increase in your blood pressure. If you develop a throbbing headache after eating or drinking, tell your healthcare professional. To prevent these problems, get a list of tyramine-rich foods to avoid from your healthcare professional while taking **ZYVOXAM**.

### How to take ZYVOXAM:

- ZYVOXAM (oral suspension) may be taken with or without food.
- Follow your doctor's instructions carefully.
- Do not stop taking your medicine until your doctor tells you to, even if you are feeling better. **ZYVOXAM** is not normally used in children and teenagers under 18 years old.
- If you develop severe diarrhea during or over 2 months after treatment with **ZYVOXAM**, call your healthcare professional immediately (see What are possible side effects from using **ZYVOXAM**? section below).
- Do not use any medicine to treat your diarrhea without first checking with your doctor.

### Usual dose:

(Adults, 18 years and older): 600 mg (30mL) twice a day for 10 to 28 days.

Your healthcare professional will tell you how long you need to take **ZYVOXAM** (oral suspension).

**Overdose:**

If you think you, or a person you are caring for, have taken too much **ZYVOXAM**, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule as prescribed by your doctor. **Do not take double doses to make up for missing a dose.**

**What are possible side effects from using ZYVOXAM?**

These are not all the possible side effects you may have when taking **ZYVOXAM**. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Headache
- Diarrhea
- Nausea
- Vomiting
- Dizziness
- Change in taste
- Fungal infection
  - white patches in mouth, tongue or throat (oral thrush)
  - for women, vaginal yeast infection with itching and irritation in the vagina, pain or burning when urinating (peeing), vaginal discharge
- Tongue discoloration
- Fever
- Insomnia
- Constipation
- Rash
- Dry mouth
- Stomach discomfort
- Increased thirst
- High blood sugar (blurred vision, unusual thirst, increased frequency and amount of urination, a fruit-like breath odor, rapid breathing)
- Low blood sugar (dizziness, headache, feeling sleepy, feeling weak, shaking, a fast heartbeat, confusion, hunger, or sweating)

- Ringing in the ear
- High blood pressure (watch your blood pressure closely)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b> <b>Blood problems</b> (decrease in the level of blood cells): Unusual bleeding or bruising, feeling very tired or weak shortness of breath, fever and chills, sore throat		√	
<b>Vision problems:</b> blurred vision, changes in colour vision, loss of vision		√	
Numbness, tingling, prickling sensations or burning pain		√	
<b>Signs of too much lactic acid in the blood</b> (lactic acidosis): feeling very tired or weak, feeling cold, severe nausea with or without vomiting, stomach pain, fast breathing, fast heartbeat, a heartbeat that does not feel normal, muscle pain or cramps			√
<b>Allergic reactions:</b> rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing; swelling of the mouth, face, lips, tongue, or throat			√
<b>Clostridium difficile colitis</b> (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
<b>Serotonin syndrome</b> (occur within several hours of starting a new			√

<p>medicine or increasing the dose of a drug you are already taking): severe headache, agitation, fever, fast heartbeat, flushing, seizures, shakiness, sweating a lot, change in balance, change in thinking clearly, severe upset stomach and throwing up, severe loose stools</p>			
<p><b>Severe Cutaneous Adverse Reactions (SCAR):</b> severe skin reactions that may also affect other organs:</p> <ul style="list-style-type: none"> <li>• Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish)</li> <li>• Swelling and redness of eyes or face</li> <li>• Flu-like feeling, fever, chills, body aches, swollen glands, cough</li> <li>• Shortness of breath, chest pain or discomfort</li> </ul>			v

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store **ZYVOXAM** (oral suspension) in controlled room temperature between 15-30°C.

Use within 21 days after reconstitution. Protect from light. Keep bottles tightly closed to protect from moisture.

Keep out of reach and sight of children.

**If you want more information about ZYVOXAM:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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