ZYVOX POWDER FOR ORAL SUSPENSION

Linezolid (100 mg/5 mL)

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What ZYVOX is used for

ZYVOX is an antibiotic. It is used to treat pneumonia, skin infections, and some bacterial infections that are resistant to other antibiotics.

How ZYVOX works

ZYVOX stops or slows the growth of bacterial cells.

Before you use ZYVOX

- *When you must not use it*

Do not use ZYVOX if you

- are allergic to linezolid or any other ingredients in this product
- are taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (e.g. phenelzine, isocarboxazid)
- have uncontrolled hypertension (high blood pressure)
- have pheochromocytoma (adrenal gland tumor)
- have thyrotoxicosis (excessive thyroid hormone)
- have carcinoid syndrome (signs and symptoms that occur secondary to carcinoid tumours)
- If you are taking any of the following medicines
  - pseudoephedrine
  - phenylpropanolamine
  - epinephrine
  - norepinephrine
  - dopamine
  - dobutamine
  - serotonin re-uptake inhibitors
  - tricyclic antidepressants
  - serotonin 5-HT1 receptor agonists
  - meperidine
  - buspirone

Pregnancy and lactation

The effect of ZYVOX in pregnant women is not known. Therefore, it should not be taken in pregnancy unless advised by your doctor

It is not known if linezolid is excreted in human milk. Therefore, ZYVOX should be taken with caution in nursing women. Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Talk to your doctor before taking ZYVOX if you

- are at increased risk for bleeding
- are at increased risk of platelet deficiency
- have kidney or liver disease
- have a pre-existing condition called myelosuppression in which your bone marrow activity is decreased
- are on medications that may decrease hemoglobin levels or platelet count
- have a history of seizures or have risk factors for seizures
- are taking any serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and opioids
- have Hyponatremia and/or Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH)
- are at high risk for life threatening systemic infections, such as those with infections related to central venous catheters in intensive care units

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

ZYVOX should not be taken with the following medicines:

- Monoamine oxidase inhibitors (e.g. phenelzine, isocarboxazid) in the last two weeks
- Sympathomimetic agents (e.g. pseudoephedrine, phenylpropanolamine)
- Vasopressive agents (e.g. epinephrine, norepinephrine)
- Dopaminergic agents (e.g. dopamine, dobutamine)
- Rifampin
- Serotonin re-uptake inhibitors
- Tricyclic antidepressants
- Serotonin 5-HT1 receptor agonists
- Meperidine or buspirone

How to use ZYVOX

How to prepare ZYVOX

Gently tap bottle to loosen powder. Add a total of 123 ml distilled water in two portions. After adding the first half, shake vigorously to wet all of the powder. Then add the second half of the water and shake vigorously to obtain uniform suspension. After constitution, each 5 mL of the suspension contains 100 mg of linezolid.

Before using, gently mix by inverting the bottle 3 to 5 times. Do not shake.

Store constituted suspension at room temperature. Use within 21 days after constitution.

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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Recommended dosage for adults and adolescents (12 years and above):

Infection	Dosage	Recommended Duration of Treatment (consecutive days)
Complicated skin and skin structure infections	600 mg every 12 hours	10-14
Community-acquired pneumonia, including concurrent bacteremia		
Nosocomial pneumonia		
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	600 mg every 12 hours	14-28
Uncomplicated skin and skin structure infections	Adults: 400 mg every 12 hours Adolescents: 600 mg every 12 hours	10-14

Recommended dosage for pediatric patients (birth through 11 years):

Infection	Dosage	Recommended Duration of Treatment (consecutive days)
Complicated skin and skin structure infections	10 mg/kg every 8 hours	10-14
Community-acquired pneumonia, including concurrent bacteremia		
Nosocomial pneumonia		
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg every 8 hours	14-28
Uncomplicated skin and skin structure infections	Below 5 years: 10 mg/kg every 8 hours 5-11 years: 10 mg/kg every 12 hours	10-14

- *When to use it*

  Use as directed by your doctor or pharmacist.

- *How long to use it*

  Continue taking for as long as your doctor recommends.

- *If you forget to use it*

  Consult your doctor or pharmacist on what you should do if you forget to use it.

  Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

  Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using ZYVOX

- *Things you must do*

  Take your medicine exactly as your doctor has told you.

  Tell all the doctors, dentists and pharmacists treating you that you are taking ZYVOX.

  Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

  Do not stop taking the medicine unless advised by your doctor.

  Do not take any new medicines without consulting your doctor.

  Do not give ZYVOX to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

  Driving and using machines

  This medicine may affect your ability to drive or use machines. If it makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, ZYVOX can cause side effects, although not everybody gets them.

You may develop diarrhoea while taking or after taking ZYVOX. If this becomes severe or persistent or you notice that your stool contains blood or mucus, you should stop taking ZYVOX immediately and consult your doctor.

If you take ZYVOX for longer periods you may get problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.

Other side effects some patients have experienced while taking ZYVOX are:

Common side effects:
- Abdominal pain/cramps
- Nausea
- Vomiting
- Diarrhea
- Moniliasis (yeast infection)
- Abnormal blood tests
- Thrombocytopenia (decreased number of platelets)
- Abnormal liver function tests

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- Headache
- Rash

Uncommon side effects:
- Pancytopenia (decreased number of red blood cells, white blood cells and platelets)
- Leucopenia (decreased number of white blood cells)
- Convulsions
- Peripheral neuropathy
- Taste alteration
- Optic neuropathy (loss of vision due to damage to the optic nerve)
- Abdominal distension
- Tongue discoloration
- Bullous skin disorders (e.g. Stevens Johnson syndrome, toxic epidermal necrolysis)
- Angioedema (swelling of the skin and mucous membranes)

Rare side effects:
- Sideroblastic anaemia (a form of anemia in which the bone marrow produces ringed sideroblasts)
- Anaphylaxis (serious allergic reaction)
- Lactic acidosis
- Superficial tooth discoloration
- Black discoloration of the tongue's surface, which appears hairy
- Toxic epidermal necrolysis (life-threatening condition characterized by extensive exfoliation of the epidermis and mucous membrane)
- Stevens-Johnson syndrome (Serious skin reaction)
- Rhabdomyolysis (breakdown of damaged muscle) - muscle pain, tenderness or weakness and dark urine)

If signs or symptoms of rhabdomyolysis (breakdown of damaged muscle) are observed, you should stop using ZYVOX and tell your doctor immediately.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my
[Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ZYVOX
- *Storage*

Keep out of the reach and sight of children.

Store below 30°C. Protect from light.

Keep bottles tightly closed to protect from moisture.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- *What it looks like*

ZYVOX oral suspension is available as a dry, white to off-white, orange-flavored granule/powder.

- *Ingredients*

  - Active ingredient:
    Linezolid

  - Inactive ingredients:
    Aspartame, citric acid, colloidal silicon dioxide, flavors, mannitol, microcrystalline cellulose and carboxymethylcellulose sodium, sodium benzoate, sodium chloride, sodium citrate, sucrose, and xanthan gum. The sodium (Na+) content is 8.52 mg/5 mL (0.4 mEq/5 mL).

- *MAL number:*

MAL26076009ACRZ

Manufacturer
Neolpharma, Inc.,
Caguas, Puerto Rico, USA

Product Registration Holder
Pfizer (Malaysia) Sdn. Bhd.
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