

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**ZYVOXID® 600 mg
Tablets**

Active ingredient

Each tablet contains: linezolid 600 mg

For a list of inactive ingredients and allergens in this medicine, see section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

To treat infections in adults and children that are caused by micro-organisms that are resistant to all other antibiotics and susceptible to linezolid; this includes infections that cause recurrent bacteremia such as

- pneumonia (cases contracted in the community and in hospital)
- skin and soft tissue infections including diabetic foot infections
- infections caused by enterococcal bacteria

Therapeutic group:

an antibiotic of the oxazolidinones group.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You are breastfeeding. This is because this medicine passes into breast milk and could affect the baby.
- You are taking or have taken within the last 14 days any medicines known as monoamine oxidase inhibitors (MAOIs) (for example phenelzine, isocarboxazid, selegiline, moclobemide). These are sometime used to treat depression or Parkinson's disease.

Special warnings regarding use of the medicine

Before treatment with Zyvoxid®, tell your doctor if:

- You have high blood pressure, whether or not you are taking medicines for this condition.
- You have been diagnosed with an overactive thyroid.
- You have a tumor of the adrenal glands or carcinoid syndrome (caused by tumors of the hormone system with symptoms of diarrhea, flushing of the skin, wheezing sounds when you breathe).
- You suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems.

Take special care with Zyvoxid® and tell your doctor if:

- You bruise and bleed easily.
- You are anemic (have a low level of red blood cells).
- You are prone to getting infections.
- You have or have had seizures.
- You have liver problems or kidney problems particularly if you are on dialysis (this medicine will be used after your dialysis treatment).

- You have diarrhea.

Children and adolescents

The use of Zyvoxid® for the treatment of children with central nervous system infections is not recommended.

Tests and follow-up

While taking this medicine, patients must have regular blood tests, particularly if they are taking medicines that may cause lower platelet counts and function or if they are taking linezolid for more than two weeks. Your doctor should monitor your eyesight if you take this medicine for an extended period (more than 28 days). There is a risk that Zyvoxid® may interact with other medicines and cause side effects such as changes in blood pressure, body temperature or heart rate. Your doctor may want to check your general health and your blood pressure before and during your treatment with this medicine or your doctor may decide that another treatment is better for you.

Other medicines and Zyvoxid®

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Particularly, tell your doctor if you are taking or have taken within the last 14 days the following medicines, as Zyvoxid® must not be taken in combination with these medicines (see 'Do not take this medicine if'):

- monoamine oxidase inhibitors (MAOIs) (for example phenelzine, isocarboxazid, selegiline, moclobemide) that are sometime used to treat depression or Parkinson's disease.

Also tell your doctor before starting this treatment if you are taking any of the following medicines:

- decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine
- some medicines used to treat asthma such as salbutamol, terbutaline, and fenoterol
- antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) such as amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, and sertraline
- medicines used to treat migraine such as sumatriptan and zolmitriptan
- medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine).
- medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine, and dobutamine
- medicines used to treat moderate to severe pain, such as pethidine
- medicines used to treat anxiety disorders, such as buspirone
- medicines that stop blood clotting, such as warfarin
- an antibiotic called rifampicin

Using this medicine and food

You can take this medicine with or without food. Swallow the medicine with some water.

During the course of this treatment, avoid large amounts of foods and drinks that contain a lot of tyramine such as wine and draft beer, yeast extracts, soybean extracts (including soy sauce) and foods that have been aged like mature cheese. This is because when combined with this medicine your blood pressure could rise. If you develop a throbbing headache after eating or drinking, tell your doctor immediately.

Pregnancy, breastfeeding and fertility

If you are pregnant, are planning to become pregnant, or if you are breastfeeding, do not use this medicine before you consult a doctor.

The effect of this medicine in pregnant women is not known. Consult your doctor before starting treatment if you are pregnant or breastfeeding. Tell your doctor immediately if you discover that you are pregnant, think you may be pregnant, or are planning to have a baby or breastfeed.

Zyvoxid® may harm your unborn baby so do not use this medicine during pregnancy unless the benefit outweighs the risk.

Do not breastfeed when taking Zyvoxid® because it passes into breast milk and could affect the baby.

Driving and using machines

This medicine may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate machines.

Caution children against riding a bicycle, playing near a road, and similar activities.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

The dose for premature babies, newborns, and children under 18 years old will be adjusted by the doctor according to the child's age and weight.

You must complete the course of treatment recommended by your doctor. Do not use this medicine often or for an extended period without consulting a doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine and your original symptoms come back, contact your doctor immediately.

Do not exceed the recommended dose.

Do not crush/split/chew because the tablets are film-coated.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember. Count the time to take the next dose from the time you took this dose, but never take a double dose!

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The serious side effects of Zyvoxid® (and their frequencies) are:

Stop taking this medicine and contact your doctor immediately in case of:

- appearance of severe skin disorders (frequency not known), swelling particularly around the face and neck (frequency not known), wheezing and/or difficulty breathing (frequency not known). These may be a sign of an allergic reaction. Severe diarrhea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in rare circumstances may become life-threatening (rare). If this happens, do not take medicines that slow or stop bowel activity.

Contact your doctor immediately in case of:

- skin reactions such as red sore skin with flaking (dermatitis) (uncommon), rash (common), itching (common)
- problems with your vision such as blurred vision (uncommon), changes in color vision (frequency not known), difficulty in seeing detail (frequency not known), or if your field of vision becomes restricted (rare)
- if you get recurrent nausea or vomiting, abdominal pain or rapid breathing (frequency not known)
- if you lose sensation or feel tingling or prickling in your arms or legs
- if you experience seizures or fits (uncommon), agitation, confusion, delirium, muscle rigidity, tremor, incoordination particularly if you are also taking antidepressants known as SSRIs (selective serotonin reuptake inhibitors) (frequency not known). (see 'Other medicines and Zyvoxid®')
- increased tendency to bleed and bruise, which is due to reduced numbers of certain cells in the blood which may affect blood clotting or lead to anemia (common)
- changes in numbers of certain cells in the blood which may affect your ability to fight infection (common).

Signs of infection include: fever (common), sore throat (uncommon), mouth ulcers (uncommon), and tiredness (uncommon).

- inflammation of the pancreas (uncommon)
- convulsions (uncommon)
- transient ischemic attacks (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) (uncommon)
- ringing in the ears (tinnitus) (uncommon)
- throbbing headache after eating or drinking
- Numbness, tingling in the limbs, and blurred vision have been reported by patients who have been given this medicine for more than 28 days.

Additional side effects

Common side effects (may affect up to 1 in 10 users):

- fungal infections especially in the mouth or vagina
- headache
- metallic taste in the mouth
- indigestion, abdominal pain, diarrhea, constipation, nausea or vomiting
- changes in blood test results (including tests measuring your liver or kidney function and blood sugar levels)
- difficulty in sleeping
- increased blood pressure
- dizziness
- localized pain
- anemia (low level of red blood cells)

Uncommon side effects (may affect up to 1 in 100 users):

- inflammation in the vagina or genital area in women
- tingling sensation or numbness
- inflammation of the veins (with Zyvoxid® IV, drip only)
- swollen, sore, or discolored tongue
- a need to urinate more often
- chills, feeling thirsty
- increased sweating
- changes in proteins, salts or enzymes in the blood which measure liver or kidney function
- low blood sodium levels
- kidney failure
- reduced level of platelets
- abdominal bloating
- increase in creatinine
- stomach pain
- changes in heart rate (for example increased heart rate)

Rare side effects (may affect up to 1 in 1,000 users):

- superficial tooth discoloration (removable with professional dental cleaning)

Side effects of unknown frequency:

- hair loss
- decrease in blood count
- weakness and/or sensory changes

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.it) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.it>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Protect from light.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, corn starch, sodium starch glycollate, hydroxypropyl cellulose, magnesium stearate, carnauba wax, Opadry White YS-1-18202-A.

What the medicine looks like and contents of the pack:

Zyvoxid®: white to off-white tablet debossed with "ZYV" on one side and "600" on the other.

Registration holder's name and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Manufacturer's name and address: Pfizer Inc, NEW YORK, 10017 USA.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 122.61.30245.01

Revised in August 2020 according to MOH guidelines.