

This medicine is dispensed with a doctor's prescription only

ZYVOXID® 600 mg Tablets



Active ingredient

Each tablet contains: linezolid 600 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and 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 bacteraemia such as:

- pneumonia (cases acquired in the community and hospitals).
- 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 breast-feeding. 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 sometimes 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 and whether or not you are being treated with medicines for this condition.
- You have been diagnosed with an overactive thyroid.
- You have a tumour of the adrenal glands or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing sounds when you breathe).
- You suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems.
- You have a history of hyponatraemia (low blood sodium levels) or you take medicines that lower blood sodium levels, e.g., certain diuretics (also called "water tablets") such as hydrochlorothiazide.
- You take opioids.

The use of certain medicines, including antidepressants and opioids, together with Zyvoxid can lead to serotonin syndrome, a potentially life-threatening condition (see under 'Drug interactions' and section 4 'Side effects').

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

- You are elderly.
- You bruise and bleed easily.
- You are anaemic (you 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 diarrhoea.

Contact your doctor immediately during treatment in case of:

- Appearance of visual disturbances such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- Loss of sensation or a sensation of tingling or pricking in your arms or legs.
- Development of diarrhoea during the treatment or after the treatment, which becomes a severe or persistent condition or your stool contains blood and/or mucus, in this situation, you should also not take medicines that slow or stop bowel movement.
- Recurrent nausea or vomiting, abdominal pain or rapid breathing.
- Unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- Feeling sick and unwell with muscle weakness, headache, confusion and memory impairment, which may indicate hyponatraemia (low blood sodium levels).

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 a reduction in platelet counts and function or if they have been taking linezolid for more than two weeks.

Patients who take this medicine for an extended period (more than 28 days) should have a vision test.

As 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 decide that another treatment is better for you.

Drug interactions

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 sometimes 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 flu or cold remedies containing pseudoephedrine or phenylpropanolamine.
- medicines used to treat asthma such as salbutamol, terbutaline, and fenoterol.
- antidepressants from the tricyclic or selective serotonin reuptake inhibitor (SSRI) group such as amitriptyline, citalopram, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine or 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.
- opioids, e.g., pethidine - medicines used to treat moderate to severe pain.
- 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 draught beer, yeast extracts, soya bean extracts (including soya 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, breast-feeding and fertility

If you are pregnant, are planning to become pregnant, or if you are breast-feeding, 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 with this medicine if you are pregnant or breast-feeding. Tell your doctor immediately if you discover that you are pregnant, think you may be pregnant, or are planning to have a baby or breast-feed.

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

Do not breast-feed 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 visual disturbances. If this happens to you, do not drive or operate machines. Caution children against riding a bicycle, playing near a road, and similar activities.

Important information about some of this medicine's ingredients

This medicine contains sodium. Zyvoxid contains less than 1 mmol sodium (23 mg) per 600 mg tablet, that is to say essentially 'sodium-free'.

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 medicine.

The dosage, treatment duration 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. Calculate 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 Zyvoxid 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 (uncommon), swelling particularly around the face and neck (uncommon), wheezing and/or difficulty breathing (rare). These may be a sign of an allergic reaction.
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis, including pseudomembranous colitis), which in rare circumstances may become life-threatening (uncommon).

Contact your doctor immediately during treatment in case of:

- skin reactions including a raised purple rash due to inflammation of the blood vessels (rare), red sore skin and flaking (dermatitis) (uncommon), rash (common), itching (common).
- appearance of problems with your vision such as blurred vision (uncommon), changes in colour vision (frequency not known), difficulty in seeing detail (frequency not known), or if your field of vision becomes restricted (rare).
- recurrent nausea or vomiting, abdominal pain or rapid breathing (rare).
- loss of sensation or a sensation of tingling or pricking in your arms or legs.
- seizures or fits (uncommon).
- serotonin syndrome (frequency not known): agitation, confusion, delirium, muscle rigidity, tremor, incoordination, seizure, rapid heartbeat, severe breathing problems, and diarrhoea (suggestive of serotonin syndrome) especially if you are also taking antidepressants from the selective serotonin reuptake inhibitor (SSRI) group or opioids (see 'Drug interactions').
- increased unexplained tendency to bruise and bleed, which is due to a decrease in certain blood cells which may affect blood clotting or lead to anaemia (common).
- changes in the levels of certain blood cells which may affect the ability of your immune system to fight infection (uncommon). Signs of infection include fever (common), sore throat (uncommon), mouth ulcers (uncommon), and tiredness (uncommon).
- rhabdomyolysis (rare): Signs and symptoms include unexplained muscle pain, tenderness, or weakness, and/or dark urine. These can be signs of a serious condition called rhabdomyolysis (muscle breakdown), which can lead to kidney damage.
- 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).
- numbness, tingling in the limbs, and blurred vision have been reported by patients who have been given this medicine for more than 28 days.
- throbbing headache after eating or drinking.

Additional side effects

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

- fungal infections especially vaginal or oral "thrush"
- headaches
- metallic taste in the mouth
- indigestion, diarrhoea, constipation, nausea or vomiting
- changes in blood test results, including tests measuring proteins, salts or enzymes which measure your liver or kidney function or blood sugar levels
- difficulty in sleeping
- increased blood pressure
- anaemia (low level of red blood cells)
- dizziness
- localised or general abdominal pain
- localised pain
- reduced level of blood platelets

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 discoloured tongue
- dry mouth
- a need to urinate more often
- chills, feeling thirsty
- increased sweating
- low blood sodium levels
- kidney failure
- abdominal bloating
- injection site pain
- increased creatinine levels
- stomach pain
- changes in heart rate (for example increased heart rate)
- decrease in blood count
- weakness and/or sensory changes

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

- superficial tooth discolouration (removable with professional dental cleaning)

Side effects of unknown frequency (the frequency of these effects has not yet been determined):

- alopecia

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.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

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 glycolate, 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 of the tablet and "600" on the other.

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

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

Revised in 08/2024