





Linezolid is an antibiotic that fights bacteria in the body.

Linezolid is used to treat different types of bacterial infections, such pneumonia, skin infections, and infections that are resistant to other antibiotics.

 $\ensuremath{\text{Linezolid}}$ may also be used for purposes other than those listed in this medication guide.

USES

Linezolid is an antibiotic used to treat certain serious bacterial infections often resistant to other antibiotics.

HOW TO USE

Inject the entire amount of each medication bag (one dose) into a vein (IV) over 30 minutes to 2 hours. Doses are usually repeated every 12 hours or as directed by your doctor. Squeeze IV bags to check for leaks. Do not use leaky IV bags. Linezolid is related to a group of drugs called MAO inhibitors. Certain foods interact with MAO inhibitors causing severe headache and increased blood pressure. This could lead to a medical emergency. See DRUG **INTERACTIONS** section. Continue to use this medication until the full-prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, use this drug at evenly spaced intervals. Learn how to store and discard needles and medical supplies safely. Inform your doctor if your condition does not improve in 10 days.

SIDE EFFECTS

Diarrhea, headache, nausea or vomiting, dizziness, trouble sleeping, or rash may occur. If these persist or worsen, notify your doctor promptly. Tell your doctor immediately if any of these serious side effects occur: pain/itching/redness or swelling at the injection site. Tell your doctor immediately if any of these unlikely but serious side effects occur: easy bruising or bleeding, severe headache, severe dizziness, vision changes, tingling or numbness of hands/feet, fever, persistent sore throat, unusual fatigue. Use of this medication for prolonged or repeated periods may result in a secondary infection (e.g., oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor your medical history, especially of: high blood pressure (hypertension), blood disorders (low blood counts), chronic infection, any allergies. Tell your doctor if you have had diarrhea and stomach pain while taking other antibiotics. This may be a symptom of a different infection (pseudomembranous colitis) that requires another medication. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

This drug should not be used with the following medications because very serious interactions may occur: apraclonidine, brimonidine, bethanidine, bupropion, buspirone, carbamazepine, dextromethorphan, entacapone, herbal products (e.g., ma huang), indoramin, meperidine, papaverine, sibutramine, SSRI antidepressants (e.g., fluoxetine, citalopram), sympathomimetics (e.g., methylphenidate, ephedrine), tolcapone, tricyclic antidepressants (e.g., amitriptyline, doxepin), "triptans" (e.g., sumatriptan, zolmitriptan). If you are currently using any of these medications, tell your doctor or pharmacist before starting linezolid. Before using this medication, tell your doctor of all prescription and nonprescription medication you may use, especially: other antibiotics, other drugs which depress the bone marrow (e.g., cancer chemotherapy), other MAO inhibitors (e.g., furazolidone, moclobemide, phenelzine, procarbazine). Check the labels on all your medicines (e.g., cough-and-cold products, diet aids) because they may contain ingredients that could increase your heart rate or blood

pressure. Avoid these products while taking this medication. Ask your pharmacist for additional information. Limit your tyramine intake while using this medication and for 2 days after stopping treatment. Also avoid foods or drinks with high tyramine content during use because the combination may cause a serious rise in your blood pressure. Foods high in tyramine include those that may change as a result of aging, fermentation, pickling, or smoking. The tyramine content of any protein-rich food (meats, fish and dairy products) may increase if stored for long periods or improperly refrigerated. Some foods high in tyramine include aged cheeses (0 to 15mg per ounce); fermented or air-dried meats (0.1 to 8mg per ounce); sauerkraut (8mg per 8 ounces); soy sauce (5mg per 1 teaspoon); tap beers (4mg per 12 ounces); red wines (0 to 6mg per 8 ounces). Total intake of tyramine should be less than 100mg per meal. Tell your doctor or pharmacist immediately if you notice symptoms of high blood pressure such as fast or pounding heartbeat, vomiting, sweating or headache, chest pain, sudden vision changes, one-sided weakness or slurred speech. Contact your healthcare professional (e.g., doctor, pharmacist or dietician) for more information, including recommendations for your diet. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE

In the event of overdosage, supportive care is advised, with maintenance of glomerular filtration. Hemodialysis may facilitate more rapid elimination of linezolid. In a Phase 1 clinical trial, approximately 30% of a dose of linezolid was removed during a 3-hour hemodialysis session beginning 3 hours after the dose of linezolid was administered. Data are not available for removal of linezolid with peritoneal dialysis or hemoperfusion. Clinical signs of acute toxicity in animals were decreased activity and ataxia in rats and vomiting and tremors in dogs treated with 3000 mg/kg/day and 2000 mg/kg/day, respectively.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Keep each medication bag in the overwrap until ready to use. Store at controlled room temperature (77 degree F or 25 degrees C) away from light and moisture. Brief storage between 59 and 86 degrees F (15 to 30 degrees C) is permitted. Protect from freezing. This medication may have a yellow color. This color may vary slightly. It is harmless and does not affect the medication.

WARNINGS

Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving linezolid. In cases where the outcome is known, when linezolid was discontinued, the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks, those with pre-existing myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or those with a chronic infection who have received previous or concomitant antibiotic therapy. Discontinuation of therapy with linezolid be considered in patients who develop or have worsening myelosuppression.



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