

DOSAGE FORMS AND STRENGTHS

Film coated tablet 600 mg

INDICATIONS AND USAGE

Xovyx is an oxazolidinone-class antibacterial indicated in adults and children for the treatment of the following infections caused by susceptible gram-positive bacteria:

- Nosocomial pneumonia
- Community-acquired pneumonia (CAP)
- Complicated skin and skin structure infections (CSSSI), including diabetic foot infections, without concomitant osteomyelitis
- Uncomplicated skin and skin structure infections
- Vancomycin-resistant enterococcus faecium infections.

Limitations of Use : Xovyx is not indicated for the treatment of gram-negative infections.

• The safety and efficacy of Xovyx formulations given for longer than 28 days have not been evaluated in controlled clinical trials.

• To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xovyx formulations and other antibacterial drugs, Xovyx should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DOSAGE AND ADMINISTRATION

| Infection | Dosage, Route, and Frequency of Administration | | |
|---|--|---|-----------------|
| | Pediatric Patients (birth through 11 years of age) | Adults and Adolescents (12 years and older) | Duration (days) |
| Nosocomial pneumonia | 10 mg/kg oral every 8 hours | 600 mg oral every 12 hours | 10 to 14 |
| Community-acquired pneumonia (CAP), including concurrent bacteremia | | | |
| Complicated skin and skin structure infections | 10 mg/kg oral every 8 hours | 600 mg oral every 12 hours | 14 to 28 |
| Vancomycin-resistant enterococcus faecium infections, including concurrent bacteremia | | | |
| Uncomplicated skin and skin structure infections | less than 5 yrs: 10 mg/kg oral every 8 hours 5–11 yrs: 10 mg/kg oral every 12 hours | Adults: 400 mg oral every 12 hours Adolescents: 600 mg oral every 12 hours | 10 to 14 |

CONTRAINDICATIONS

- Known hypersensitivity to linezolid or any of the other product components.
- Patients taking any monoamine oxidase inhibitors (MAOI) or within two weeks of taking an MAOI.

WARNINGS AND PRECAUTIONS

• Myelosuppression: monitor complete blood counts weekly. Consider discontinuation in patients who develop or have worsening myelosuppression. • Peripheral and optic neuropathy: reported primarily in patients treated for longer than 28 days. If patients experience symptoms of visual impairment, prompt ophthalmic evaluation is recommended. • Serotonin syndrome: patients taking serotonergic antidepressants should receive Xovyx only if no other therapies are available. Discontinue serotonergic antidepressants and monitor patients for signs and symptoms of both serotonin syndrome and antidepressant discontinuation. • A mortality imbalance was seen in an investigational study in linezolid-treated patients with catheter-related bloodstream infections. • Clostridioides difficile-Associated Diarrhea: evaluate if diarrhea occurs. • Potential interactions producing elevation of blood pressure: monitor blood pressure. • Hypoglycemia: postmarketing cases of symptomatic hypoglycemia have been reported in patients with diabetes mellitus receiving insulin or oral hypoglycemic agents.

PREGNANCY

There are no adequate and well-controlled studies in pregnant women. Xovyx should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

ADVERSE REACTIONS

Most common adverse reactions (>5% of adult and/or pediatric patients treated with Linezolid) include: diarrhea, vomiting, headache, nausea, and anemia.

SPECIAL PRECAUTIONS FOR STORAGE

This medicinal product does not require any special storage conditions.

References:
1. Sotgiu G, Centis R, D'Ambrosio L, Alfano R, JMW, Anger HA, Caminero JA, Castiglia P, De Lorenzo S, Ferrara G, Koh WJ, Schecter GF. Efficacy, safety and tolerability of linezolid containing regimens in treating MDR-TB and XDR-TB: systematic review and meta-analysis. *European Respiratory Journal*. 2012 Dec 1;30(6):1430-42. 2. Mermel LA, Alon M, Bouza E et al. Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2009;49(1):1-45. doi:10.1086/599376 3. Stein GE, Wells EM. The importance of tissue penetration in achieving successful antimicrobial treatment of nosocomial pneumonia and complicated skin and soft-tissue infections caused by methicillin-resistant *Staphylococcus aureus*; vancomycin and linezolid. *Current medical research and opinion*. 2010 Mar 1;26(3):571-88. 4. Shoustar AH, Nugent K. Diagnosis and treatment of adults with community-acquired pneumonia. An official clinical practice guideline of the American thoracic society and infectious diseases society of America. *The Southwest Respiratory and Critical Care Chronicles*. 2020 Feb 7;8(3):1-6. 5. Li J, Zhao QH, Huang KC, Li ZQ, Zhang LY, Qin DY, Pan F, Huang WX. Linezolid vs. vancomycin in treatment of methicillin-resistant staphylococcus aureus infections: a meta-analysis. *Eur Rev Med Pharmacol Sci*. 2017 Oct 1;21(17):3974-9. 6. Turner JM, Hakeem LM, Lockman KA, Bhattacharya DN, Campbell IW. Diabetic MRSA foot infection—role of linezolid therapy. *The British Journal of Diabetes & Vascular Disease*. 2004 Jan;4(1):44-6 7. Pontefract BA, Rovelsky SA, Madaras-Kelly KJ. Linezolid to treat urinary tract infections caused by vancomycin-resistant Enterococcus. *SAGE Open Medicine*. 2020 Nov;8:2050312120970743. 8. Eckmann C, Nathwani D, Lawson W, Corman S, Solem C, Stephens J, Macchilig C, Li J, Charbonneau C, Baillon-Plot N, Haider S. Comparison of vancomycin and linezolid in patients with peripheral vascular disease and/or diabetes in an observational European study of complicated skin and soft-tissue infections due to methicillin-resistant *Staphylococcus aureus*. *Clinical Microbiology and Infection*. 2015 Sep 1;21:533-9. 9. Uptodate (2020). Linezolid: Drug information

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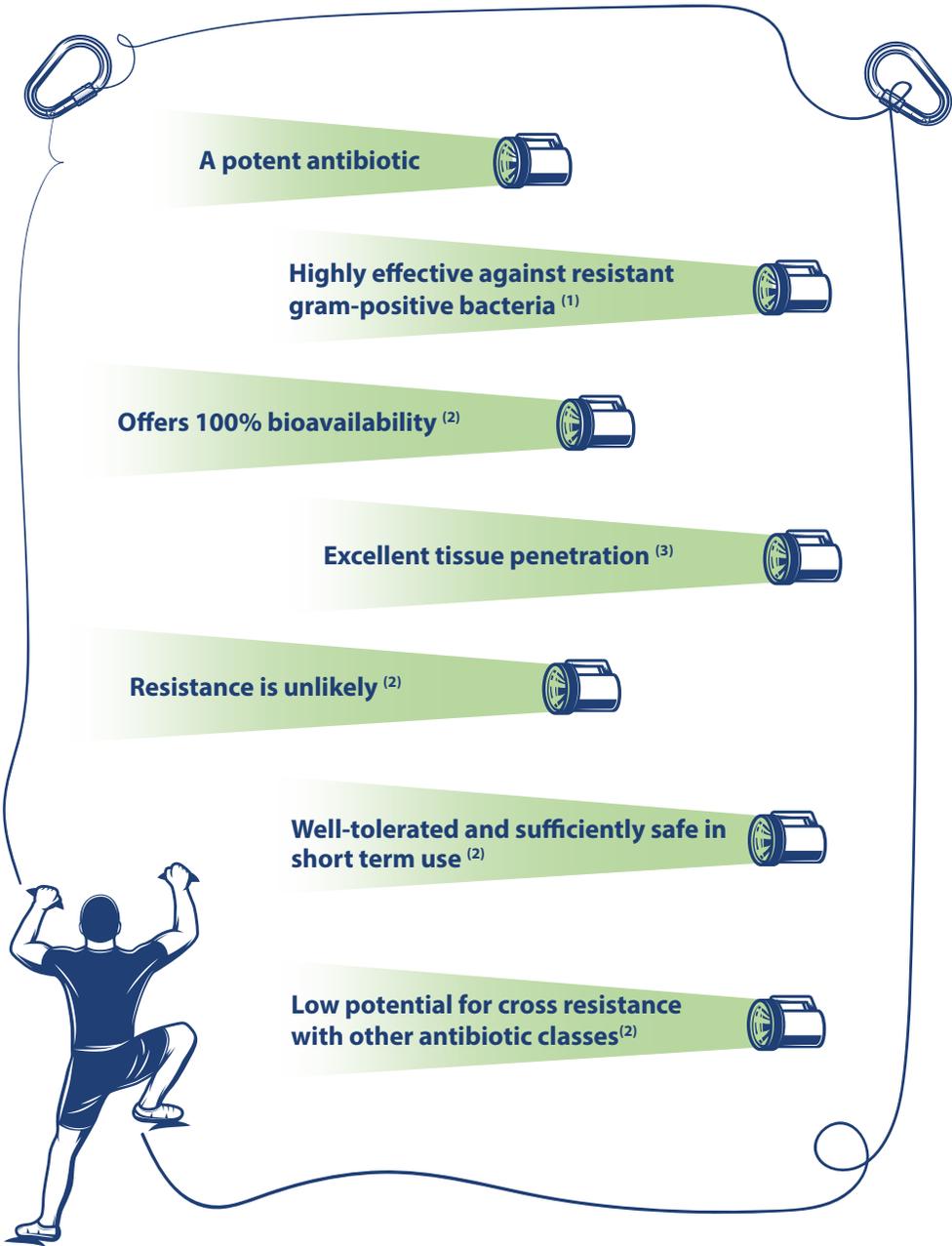
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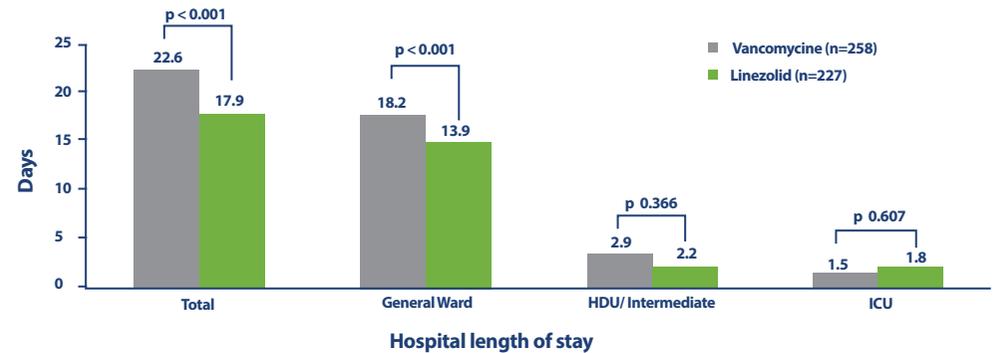
XOVYX

LINEZOLID
F.C. tablet 600mg

Comparative efficacy



- ✗ Highly effective in nosocomial infections due to MRSA, compared to vancomycin. ^(4,5)
- ✗ More effective than aminopenicillin/beta lactamase inhibitors for treating diabetic foot infection. ⁽⁶⁾
- ✗ Effective in CRBSI (catheter-related blood stream infection) due to ampicillin- and vancomycin-resistant enterococci. ⁽²⁾
- ✗ Effective as comparator antibiotics for the treatment of mild vancomycin-resistant enterococcus urinary tract infection. ⁽⁷⁾
- ✗ Linezolid reduces length of treatment and hospitalization days, compared to vancomycin.



Hospital length of stay in patients with methicillin-resistant *Staphylococcus aureus* complicated skin and soft-tissue infections and peripheral vascular disease and/or diabetes receiving vancomycin or linezolid (propensity-score weighted). HDU, high dependency unit; ICU, intensive care unit.

