
A WORLD OF POSSIBILITIES
E.Rx 70653
E.Rx 70660
750 mg
TIVOXA® 750
Levofloxacin
500 mg
TIVOXA® 500
Levofloxacin
TIVOXA
Levofloxacin F.C. tablets 500, 750 mg

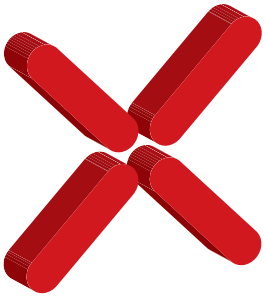
TIVOXA

Levofloxacin F.C. tablets 500, 750 mg

Tivoxa (levofloxacin)

DOSAGE FORMS AND STRENGTHS :

500 mg | 750 mg — Tablets



WARNING: Fluoroquinolones, including Tivoxa®, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants.

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

INDICATION AND DOSAGE

Indication	Daily dose regimen (according to severity)	Duration Of treatment
Acute bacterial sinusitis	500 mg once daily	10 -14 days
Acute bacterial exacerbations of chronic bronchitis	500 mg once daily	7 – 10 days
Community-acquired pneumonia	500 mg once or twice daily	7 – 14 days
Pyelonephritis	500 mg once daily	7-10 days
Uncomplicated cystitis	250 mg once daily	3 days
Complicated urinary tract infections	500 mg once daily	7 – 14 days
Chronic bacterial prostatitis	500 mg once daily	28 days
Complicated Skin and soft tissue infections	500mg once or twice daily	7 – 14 days
Inhalation Anthrax	500 mg once daily	8 weeks

SPECIAL POPULATIONS

Impaired renal function (creatinine clearance ≤ 50 ml / min).

	Dose regimen		
	250 mg / 24 h	**500 mg / 24 h**	**500 mg /12 h**
Creatinine clearance	first dose: 250 mg	first dose : 500 mg	first dose : 500 mg
50-20 ml / min	then : 125 mg / 24 h	then : 250 mg / 24 h	then : 250 mg / 12 h
19 – 10 ml / min	then : 125 mg / 48 h	then : 125 mg / 24 h	then : 125 mg / 12 h
< 10 ml / min (including haemodialysis and 1 CAPD	then : 125 mg / 48 h	then : 125 mg / 24 h	then : 125 mg / 24 h

CONTRAINDICATIONS

Known hypersensitivity to Levofloxacin or other quinolones

WARNINGS AND PRECAUTIONS

- Risk of tendinitis and tendon rupture is increased. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroids, and in patients with kidney, heart or lung transplants. Discontinue if pain or inflammation in a tendon occurs.
- Anaphylactic reactions and allergic skin reactions, serious, occasionally fatal, may occur after first dose.
- Hematologic (including agranulocytosis, thrombocytopenia), and renal toxicities may occur after multiple doses.
- Hepatotoxicity: severe, and sometimes fatal, hepatotoxicity has been reported. Discontinue immediately if signs and symptoms of hepatitis occur.
- Central nervous system effects, including convulsions, anxiety, confusion, depression, and insomnia may occur after the first dose. Use with caution in patients with known or suspected disorders that may predispose them to seizures or lower the seizure threshold.
- Clostridium difficile-associated colitis: evaluate if diarrhea occurs.
- Peripheral neuropathy: discontinue if symptoms occur in order to prevent irreversibility.
- Prolongation of the QT interval and isolated cases of torsade de pointes have been reported. Avoid use in patients with known prolongation, those with hypokalemia, and with other drugs that prolong the QT interval.

ADVERSE REACTIONS

The most common reactions (≥3%) were nausea, headache, diarrhea, insomnia, constipation and dizziness.

USE IN SPECIFIC POPULATIONS

- **Geriatrics:** Severe hepatotoxicity has been reported. The majority of reports describe patients 65 years of age or older . May have increased risk of tendinopathy (including rupture), especially with concomitant corticosteroid use . May be more susceptible to prolongation of the QT interval.
- **Pediatrics:** Musculoskeletal disorders (arthralgia, arthritis, tendinopathy, and gait abnormality) seen in more levofloxacin-treated patients than in comparator. Shown to cause arthropathy and osteochondrosis in juvenile animals . Safety in pediatric patients treated for more than 14 days has not been studied. Risk-benefit appropriate only for the treatment of inhalational anthrax (post-exposure)

references :
1.Uptodate (2020). Levofloxacin:Drug informationhttps://www.uptodate.com/contents/Levofloxacin-drug-information/.
2.https://www.fda.gov/files/drugs/published/Levaquin-Label.pdf

- Broad spectrum antibiotic
- Superior target penetration
- Provide high AUC/MIC ratios for complete bacterial eradication
- High bioavailability and rapid absorption
- Safer alternative in cases of reaction to other quinolones
- Convenient once a day dosage regimen

TIVOXA

Levofloxacin F.C. tablets 500, 750 mg

ACTOVERCO

Together for a healthy future

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