QUINOCIP TABLETS

(Ciprofloxacin 250 mg & 500 mg)

COMPOSITION

Each Quinocip 250 mg tablet contains ciprofloxacin 250 mg (as ciprofloxacin hydrochloride). Each Quinocip 500 mg tablet contains ciprofloxacin 500 mg (as ciprofloxacin hydrochloride).

DESCRIPTION / PHARMACOLOGY

Ciprofloxacin is a broad-spectrum fluoroquinolone antibacterial agent. It inhibits bacterial DNA gyrase (topoisomerase II) and topoisomerase IV, enzymes required for bacterial DNA replication, transcription, repair and recombination. It is bactericidal against susceptible organisms. Antibacterial therapy should be guided by culture and susceptibility results wherever possible.

INDICATIONS

Treatment of infections caused by susceptible bacteria, according to local approved labeling, including selected urinary tract infections, bacterial prostatitis, respiratory tract infections, skin and soft-tissue infections, bone and joint infections, infectious diarrhea, typhoid fever and certain intra-abdominal infections in combination with appropriate agents. Other labeled uses may include post-exposure inhalational anthrax and plague.

For acute bacterial sinusitis, acute uncomplicated cystitis or acute exacerbation of chronic bronchitis, reserve use for patients with no suitable alternative because of the risk of serious adverse effects.

DOSAGE AND ADMINISTRATION

For oral administration. Adult dosing depends on infection type, severity, organism, renal function and clinical response. Common regimens use 250-750 mg every 12 hours; the treatment duration varies by indication. Use only the physician-prescribed dose and duration. The 250 mg and 500 mg presentations are not interchangeable without dose adjustment.

Tablets may be taken with or without food and should be swallowed with water. Do not take with milk, yogurt or calcium-fortified juice alone. Maintain adequate hydration. Separate from antacids containing magnesium/aluminum, sucralfate, iron, zinc, calcium supplements and multivalent-cation products: administer ciprofloxacin at least 2 hours before or 6 hours after these products.

Dose adjustment is required in renal impairment. Pediatric use is restricted to specific indications and requires specialist assessment. If a dose is missed, follow the prescriber's instructions; do not double doses.

CONTRAINDICATIONS

Hypersensitivity to ciprofloxacin, other quinolones or product ingredients. Concomitant use with tizanidine is contraindicated.

IMPORTANT WARNINGS

Fluoroquinolones can cause disabling and potentially irreversible adverse effects, including tendinitis/tendon rupture, peripheral neuropathy and central nervous system or psychiatric effects. Stop treatment and seek medical advice immediately if tendon pain/swelling, numbness, burning, tingling, weakness, seizures, severe mood or mental changes develop. Tendon risk is greater in older adults, corticosteroid users and transplant recipients.

Ciprofloxacin may worsen myasthenia gravis; avoid in patients with this condition. Serious hypersensitivity reactions, including anaphylaxis, may occur even after the first dose.

PRECAUTIONS

Use cautiously in patients with seizure disorders, psychiatric illness, renal impairment, QT prolongation or arrhythmia risk, electrolyte disturbances, diabetes, or history/risk factors for aortic aneurysm. Monitor for dysglycemia, photosensitivity, severe or bloody diarrhea (possible C. difficile infection), liver injury and signs of secondary infection. In patients with suspected aortic aneurysm symptoms, obtain urgent medical care.

Ciprofloxacin may cause dizziness or impaired alertness; caution when driving or using machinery. Avoid unnecessary ultraviolet exposure. Use only for proven or strongly suspected bacterial infections to limit antimicrobial resistance.

DRUG INTERACTIONS

Tizanidine is contraindicated. Interactions may occur with theophylline, warfarin, methotrexate, phenytoin, cyclosporine, oral antidiabetic drugs, corticosteroids, medicines that prolong QT interval and caffeine. Ciprofloxacin inhibits CYP1A2; additional monitoring or dose modification may be necessary with interacting drugs. Oral mineral preparations decrease absorption as described under administration.

PREGNANCY AND LACTATION

Use during pregnancy only after individualized benefit-risk assessment. Ciprofloxacin passes into breast milk; consider infant exposure and the need for treatment when deciding whether to breastfeed or temporarily interrupt it. Consult a healthcare professional.

PEDIATRIC AND GERIATRIC USE

In children, ciprofloxacin is not routinely first-line treatment because of musculoskeletal adverse-event concerns; use only when indicated. Elderly patients may have increased risks of tendon injury, QT-related effects and impaired renal clearance.

ADVERSE REACTIONS

Commonly reported reactions include nausea, diarrhea, vomiting, abdominal discomfort, headache, dizziness and rash. Serious reactions may include tendon rupture, peripheral neuropathy, seizures, psychiatric symptoms, severe allergic or skin reactions, arrhythmias, abnormal blood glucose, hepatic injury, C. difficile-associated diarrhea and kidney injury. Seek immediate medical assistance for serious symptoms.

OVERDOSAGE

Seek urgent medical attention. Provide supportive care, monitor renal function, hydration and electrocardiogram as clinically appropriate. There is no specific antidote. Dialysis removes only a small amount of ciprofloxacin.

STORAGE

Store according to the approved product label, protected from excessive heat and moisture. Keep out of reach of children. Dispense only on prescription.

PRESENTATION

Quinocip Tablets 250 mg: pack of 10 tablets.
Quinocip Tablets 500 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.