

Flocet®

Ofloxacin

Description: Ofloxacin (Flocet®) is a synthetic 4-fluoroquinolone antibacterial agent with bactericidal activity against a wide range of gram-negative and gram-positive organisms.

Mode of action: Ofloxacin is thought to exert bactericidal effect by inhibiting DNA gyrase, an essential enzyme that is critical catalyst in the duplication, transcription and repair of bacterial DNA.

Pharmacokinetics: Following oral administration ofloxacin is rapidly and well absorbed from G.I. tract. The bioavailability of ofloxacin in the tablet formulation is approximately 98%. It is widely distributed into body tissues and fluids. The half-life is about 4.6 to 6.9 hours. Upto 80% of an oral dose of ofloxacin is eliminated in the urine as the parent compound within 48 hours.

Composition: Flocet® 200 mg Tablet: Each film coated tablet contains ofloxacin USP 200 mg.

Flocet® 400 mg Tablet: Each film coated tablet contains ofloxacin USP 400 mg.

Indications: Flocet tablets are indicated for the treatment of adults with mild to moderate infections caused by susceptible strains.

Lower Respiratory Tract: Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae* or *Streptococcus pneumoniae*. Community-acquired Pneumonia due to *Haemophilus influenzae* or *Streptococcus pneumoniae*.

Gastrointestinal Tract: Enteric fever due to *Salmonella* spp. and multiresistant strains of *S. typhi*.

Skin and skin structures: Uncomplicated skin and skin structure infections due to *Staphylococcus aureus*, *Streptococcus pyogenes* or *Proteus mirabilis*.

Sexually Transmitted Diseases: Acute Uncomplicated urethral and cervical gonorrhoea due to *Neisseria gonorrhoeae*.

Nongonococcal urethritis and cervicitis due to *Chlamydia trachomatis*.

Mixed infections of the urethra and cervix due to *Chlamydia trachomatis* and *Neisseria gonorrhoea*.

Urinary Tract: Uncomplicated cystitis due to *Citrobacter diversus*, *Enterobacter aerogenes*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*.

Complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Citrobacter diversus*, Prostate: Prostatitis due to *Escherichia coli*.

Dosage and administration

Ofloxacin Dosage Guidelines				
Infection	Unit dose	Frequency	Duration	Daily dose
Acute bacterial exacerbation of chronic bronchitis	400 mg	Every 12 hours	10 days	800 mg
Community-acquired pneumonia	400 mg	Every 12 hours	10 days	800 mg
Typhoid fever	200 mg	Every 12 hours	5 days	400 mg
Uncomplicated skin & skin structure infections	400 mg	Every 12 hours	10 days	800 mg

Ofloxacin Dosage Guidelines				
Infection	Unit dose	Frequency	Duration	Daily dose
Acute, uncomplicated urethral and cervical gonorrhea	400 mg	single dose	1 day	400 mg
Nongonococcal cervicitis / urethritis due to <i>C. trachomatis</i>	300 mg	Every 12 hours	7 days	600 mg
Mixed infection of the urethra and cervix due to <i>C. trachomatis</i> & <i>N. gonorrhoeae</i>	300 mg	Every 12 hours	7 days	600 mg
Acute pelvic inflammatory disease	400 mg	Every 12 hours	10 to 14 days	800 mg
Uncomplicated cystitis due to <i>E. coli</i> or <i>K. pneumoniae</i>	200 mg	Every 12 hours	3 days	400 mg
Uncomplicated cystitis due to other approved pathogens	200 mg	Every 12 hours	7 days	400 mg
Complicated UTIs	200 mg	Every 12 hours	7 days	400 mg
Prostatitis due to <i>E. coli</i>	300 mg	Every 12 hours	6 weeks	600 mg
Multi-Drug Resistant Tuberculosis	400 mg	Every 12 hours	Up to symptom relief	800 mg

Contraindications: Ofloxacin should not be used in patients with known hypersensitivity to 4-quinolone antibacterials. It is contraindicated in patients with a history of epilepsy or with a lowered seizure threshold. Ofloxacin is contraindicated in children or growing adolescents, and in pregnant or breast feeding women.

Adverse reaction: Gastrointestinal and central nervous system reactions are more common. Nausea, vomiting, abdominal pain, diarrhoea and gastrointestinal distress are gastrointestinal adverse effects. common central nervous system reactions are headache, dizziness and insomnia.

Precaution and warnings: Patients being treated with Ofloxacin should not expose themselves unnecessarily to strong sunlight and should avoid UV rays. Caution is recommended if the drug is to be used in psychotic patients or in patients with a history of psychiatric disease.

Drug interactions: Cationic antacids and iron.

Storage: Keep medicines out of the reach of children. Store at room temperature and protect from light & moisture.

Packaging

Flocet® 200 mg Tablet: Each carton contains 10X2 tablets in blister pack.

Flocet® 400 mg Tablet: Each carton contains 10X1 tablets in blister pack.



Manufactured by
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 Rupatali, Barishal, Bangladesh.
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