

# 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  
**Opsonin Pharma Limited**  
 Rupatali, Barishal, Bangladesh.  
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