

OFFRY – 400 / 200 / 100 DT TABLETS & OFFRY SUSPENSION

COMPOSITION

OFFRY-200 Tablets

Each film-coated tablet contains Ofloxacin 200 mg

OFFRY-400 Tablets

Each film-coated tablet contains Ofloxacin 400 mg

OFFRY—100 DT Tablets

Each Dispersible tablet contains Ofloxacin 100 mg

OFFRY SUSPENSION

Each 5ml contains
Ofloxacin 50 mg

INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ofloxacin tablets and other antibacterial drugs, ofloxacin tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Ofloxacin tablets are indicated for the treatment of adults with mild to moderate infections (unless otherwise indicated) caused by susceptible strains of the designated microorganisms in the infections listed below.

Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae* or *Streptococcus pneumoniae*.

Community-acquired Pneumonia due to *Haemophilus influenzae* or *Streptococcus pneumoniae*.

Uncomplicated skin and skin structure infections due to *methicillin-susceptible Staphylococcus aureus*, *Streptococcus pyogenes*, or *Proteus mirabilis*.

Acute, uncomplicated urethral and cervical gonorrhea 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 gonorrhoeae*.

Acute pelvic inflammatory disease (including severe infection) due to *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

NOTE: If anaerobic microorganisms are suspected of contributing to the infection, appropriate therapy for anaerobic pathogens should be administered.

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**, or *Pseudomonas aeruginosa**.

Prostatitis due to *Escherichia coli*.

* = Although treatment of infections due to this organism in this organ system demonstrated a clinically significant outcome, efficacy was studied in fewer than 10 patients.

Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing the infection and to determine their susceptibility to ofloxacin. Therapy with ofloxacin may be initiated before results of these tests are known; once results become available, appropriate therapy should be continued.

As with other drugs in this class, some strains of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with ofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information not only on the therapeutic effect of the antimicrobial agent but also on the possible emergence of bacterial resistance.

DOSAGE AND ADMINISTRATION

ADULT DOSAGE

The usual dose of ofloxacin tablets is 200 mg to 400 mg orally every 12 h as described in the following dosing chart. These recommendations apply to patients with normal renal function (i.e., creatinine clearance > 50 mL/min).

Infection†	Unit Dose	Frequency	Duration	Daily Dose
Acute Bacterial Exacerbation of Chronic Bronchitis	400 mg	q12h	10 days	800 mg
Comm. Acquired Pneumonia	400 mg	q12h	10 days	800 mg
Uncomplicated Skin and Skin Structure Infections	400 mg	q12h	10 days	800 mg
Acute, Uncomplicated Urethral and Cervical Gonorrhoea	400 mg	single dose	1 days	400 mg
Nongonococcal Cervicitis/Urethritis due to C. trachomatis	300 mg	q12h	7 days	600 mg
Mixed Infection of the urethra and cervix due to C. trachomatis and N. gonorrhoeae	300 mg	q12h	7 days	600 mg
Acute Pelvic Inflammatory Disease	400 mg	q12h	10-14 days	800 mg
Uncomplicated Cystitis due to E. coli or K. pneumoniae	200 mg	q12h	3 days	400 mg
Uncomplicated Cystitis due to other approved pathogens	200 mg	q12h	7 days	400 mg
Complicated UTI's	200 mg	q12h	10 days	400 mg
Prostatitis due to E.Coli	300 mg	q12h	6 weeks	600 mg

† DUE TO THE DESIGNATED PATHOGENS

Antacids containing calcium, magnesium, or aluminum; sucralfate; divalent or trivalent cations such as iron; or multivitamins containing zinc; or didanosine should not be taken.

Patients with Impaired Renal Function

Dosage should be adjusted for patients with a creatinine clearance < 50 mL/min. After a normal initial dose, dosage should be adjusted as follows:

For Use of registered medical practitioner or a hospital only

Creatinine Clearance	Maintenance Dose	Frequency
20-50 mL/min	the usual recommended unit dose	q24h
< 20 mL/min	½ the usual recommended unit dose	q24h

When only the serum creatinine is known, the following formula may be used to estimate creatinine clearance.

$$\text{Men: Creatinine clearance (mL/min) = } \frac{\text{Weight (kg)} \times (140 - \text{age})}{72 \times \text{serum creatinine (mg/dL)}}$$

Women: 0.85 x the value calculated for men.

The serum creatinine should represent a steady-state of renal function.

Patients with Cirrhosis

The excretion of ofloxacin may be reduced in patients with severe liver function disorders (e.g., cirrhosis with or without ascites). A maximum dose of 400 mg of ofloxacin per day should therefore not be exceeded.

CONTRAINDICATIONS

Ofloxacin tablets is contraindicated in persons with a history of hypersensitivity associated with the use of ofloxacin or any member of the quinolone group of antimicrobial agents.

PACKAGING INFORMATION

- OFFRY-200 Tablets**.....Blister pack of 10 Tablets
- OFFRY-400 Tablets**Blister pack of 5 Tablets
- OFFRY-100 DT Tablets**Blister pack of 10 Tablets
- OFFRY- SUSPENSION**60ML pet bottle