

# SPARATEC

Sparfloxacin

## Composition

Each film coated tablet contains Sparfloxacin 200 mg.

## Description

Sparfloxacin is an aminofluoroquinolone. It is chemically designated as 5- amino -1- cyclopropyl -7- (cis - 3,5- dimethyl -1- piperazinyl) 6,8 difluoro -1,4-dihydro -4- oxo -3- quinolone carboxylic acid. It is a yellow crystalline powder, its empirical formula is  $C_{19}H_{22}F_2N_4O_3$  and its molecular weight is 392.4. It is hydrophobic; its aqueous solubility is <0.04 g/L at pH 1 and <0.2 g/L at pH 7.4.

## Pharmacokinetics:

### Absorption

Absorption of Sparfloxacin begins on oral administration. The absorption of Sparfloxacin is not affected by food.

### Distribution

Sparfloxacin concentration in the extra-vascular fluid is similar to plasma concentrations. The distribution of Sparfloxacin in nasal mucosa and sinus mucosa is particularly high. In the pulmonary system, the concentrations observed are higher than the MIC of the infecting bacterial species that are susceptible to Sparfloxacin. Plasma protein binding is about 45%.

### Metabolism

Sparfloxacin is metabolized by the liver, primarily by phase II glucuronidation, to form a glucuronide conjugate. Its metabolism does not utilize or interfere with cytochrome-mediated oxidation, in particular cytochrome P450.

### Elimination

The terminal plasma elimination half - life is about 20 hours. No significant differences in pharmacokinetics have been observed in elderly subjects. The terminal plasma elimination half life was 35 to 40 hours in subject with severe renal insufficiency (creatinine clearance <30 ml/min). The terminal plasma elimination half is unchanged in subject with hepatic insufficiency.

## Microbiology

Sparfloxacin has *in vitro* activity against a wide range of gram negative and gram-positive microorganisms. Sparfloxacin exerts its antibacterial activity by inhibiting DNA gyrase, a bacterial topoisomerase. It has been shown to be active against most strains of the following microorganisms, both *in vitro* and in clinical infections as

### Aerobic gram-positive microorganisms

*Staphylococcus aureus*, *Streptococcus pneumoniae* (penicillin-susceptible strains), *Streptococcus agalactiae*, *Streptococcus pneumoniae* (penicillin-resistant strains), *Streptococcus pyogenes*, *Viridans* group streptococci

### Aerobic gram-negative microorganisms

*Enterobacter cloacae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Acinetobacter anitratus*, *Acinetobacter lwoffii*, *Citrobacter diversus*, *Enterobacter aerogenes*, *Klebsiella oxytoca*, *Legionella pneumophila*, *Morganella morganii*, *Proteus mirabilis*, *Proteus vulgaris*

### Other microorganisms

*Chlamydia pneumoniae*, *Mycoplasma pneumoniae*

### ▫ **Indications:**

- **Community-acquired pneumonia** caused by *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae*, or *Streptococcus pneumoniae*
- **Acute bacterial exacerbations of chronic bronchitis** caused by *Chlamydia pneumoniae*, *Enterobacter cloacae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, or *Streptococcus pneumoniae*

**Dosage and administration:**

- Lower respiratory tract infections including community acquired pneumonia and acute bacterial exacerbation of chronic bronchitis: 400 mg as a single dose on the first day followed by 200 mg each day for 10 days
- The recommended daily dose of Sparatec in patients with renal impairment (creatinine clearance <50 mL/min) is two 200-mg tablets taken on the first day as a loading dose. Thereafter, one 200-mg tablet should be taken every 48 hours for a total of 9 days of therapy (6 tablets).
- Sparfloxacin can be taken with or without food preferably in the morning.

**Side effects**

- Cutaneous allergy and photosensitivity.
- Mild digestive disorders: nausea, vomiting, abdominal pain and diarrhoea.
- Others: numbness, paraesthesia, malaise and conjunctivitis may rarely occur.
- As with other quinolones, hypoglycemia may rarely occur (especially in elderly patient with renal dysfunction and or diabetes)
- Rare cases of headache and sleep disorders (insomnia) are reported at the beginning of the treatment. Convulsion, tremors and hallucination may rarely occur.

**Precautions**

- As with other quinolones it is recommended that exposure to sunlight and to ultraviolet radiation should be avoided during treatment and for 3 days after the end of treatment to decrease the risk of photosensitivity.
- Quinolones should not be used during pregnancy or while breast feeding

**Contraindications**

Sparatec is contraindicated in patient with known hypersensitivity to quinolones.

**Packing**

Box of 2 strips each containing 6 tablets.

**Manufactured By**

Unipharma – El Obour City Cairo –Egypt.