



# VILOC

(Ciprofloxacin HCl)

TABLETS  
DRY POWDER FOR SUSPENSION

## COMPOSITION

### VILOC 250mg TABLETS

Each film-coated tablet contains:  
Ciprofloxacin (as HCl) USP.....250mg

### VILOC 500mg TABLETS

Each film-coated tablet contains:  
Ciprofloxacin (as HCl) USP.....500mg

### VILOC DRY POWDER FOR SUSPENSION 125mg

Each 5ml of reconstituted suspension contains:  
Ciprofloxacin taste masked granules eq. to Ciprofloxacin USP.....125mg

### VILOC DRY POWDER FOR SUSPENSION 250mg

Each 5ml of reconstituted suspension contains:  
Ciprofloxacin taste masked granules eq. to Ciprofloxacin USP.....250mg

## PROPERTIES

Ciprofloxacin HCl is of semi synthetic origin and belongs to quinolone carboxylic acid. It belongs to DNA gyrase inhibitor pharmacological group on the basis of mechanism of action and also classified in antibiotics pharmacological group. Ciprofloxacin HCl is effective against many gram positive and gram negative bacteria, including some strains resistant to penicillins, cyclosporins and aminoglycosides.

## INDICATIONS AND USAGE

VILOC is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions and patient populations listed below:

### ADULTS

**Urinary Tract Infections** caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cocci*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, or *Enterococcus faecalis*.

**Acute Uncomplicated Cystitis** in females caused by *Escherichia coli* or *Staphylococcus saprophyticus*

**Chronic Bacterial Prostatitis** caused by *Escherichia coli* or *Proteus mirabilis*.

**Lower Respiratory Tract Infections** caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cocci*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, or *Streptococcus pneumoniae*. Also, *Moraxella catarrhalis* for the treatment of acute exacerbations of chronic bronchitis.

**NOTE:** Although effective in clinical trials, ciprofloxacin HCl is not a drug of first choice in the treatment of presumed or confirmed pneumonia secondary to *Streptococcus pneumoniae*.

**Acute Sinusitis** caused by *Haemophilus influenzae*, *Streptococcus pneumoniae*, or *Moraxella catarrhalis*.

**Skin and Skin Structure Infections** caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus Vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* (Methicillin-susceptible), *Staphylococcus epidermidis*, or *Streptococcus pyogenes*.

**Bone and Joint Infections** caused by *Enterobacter cocci*, *Serratia marcescens*, or *Pseudomonas aeruginosa*.

**Complicated Intra-Abdominal Infections** (Used in combination with metronidazole) caused by *Escherichia coli*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Klebsiella pneumoniae*, or *Bacteroides fragilis*.

**Infectious Diarrhoea** caused by *Escherichia coli* (Enterotoxigenic strains), *Campylobacter jejuni*, *Shigella boydii*, *Shigella dysenteriae*, *Shigella flexneri* or *Shigella sonnei* when antibacterial therapy is indicated.

**Typhoid Fever** (Enteric Fever) caused by *Salmonella typhi*.

**NOTE:** The efficacy of ciprofloxacin HCl in the eradication of the chronic typhoid carrier state has not been demonstrated.

**Uncomplicated Cervical and Urethral Gonorrhoea** due to *Neisseria gonorrhoea*

### CHILDREN (1 to 17 years of age)

**Complicated Urinary Tract Infections and Pyelonephritis** due to *Escherichia coli*

**Cystic Fibrosis\*** (For Children above 5 years of age)

\*BNF March 2009

## DOSAGE AND ADMINISTRATION

Unless otherwise prescribed, the following guideline doses are recommended:

### ADULTS

#### URINARY TRACT INFECTIONS

- Acute uncomplicated.....250mg twice daily, 3 days
- Mild/Moderate.....250mg twice daily, 7 to 14 days
- Severe/Complicated.....500mg twice daily, 7 to 14 days

#### CHRONIC BACTERIAL PROSTATITIS

- Mild/Moderate.....500mg twice daily, 28 days

#### LOWER RESPIRATORY TRACT INFECTIONS

- Mild/Moderate.....500mg twice daily, 7 to 14 days
- Severe/Complicated.....750mg twice daily, 7 to 14 days

#### ACUTE SINUSITIS

- Mild/Moderate.....500mg twice daily, 10 days

#### SKIN AND SKIN STRUCTURE INFECTIONS

- Mild/Moderate.....500mg twice daily, 7 to 14 days
- Severe/Complicated.....750mg twice daily, 7 to 14 days

#### BONE AND JOINT INFECTIONS

- Mild/Moderate.....500mg twice daily  $\geq$  4 to 6 Weeks
- Severe/Complicated.....750mg twice daily  $\geq$  4 to 6 Weeks

#### INTRA-ABDOMINAL INFECTIONS

- Complicated.....500mg twice daily, 7 to 14 days

#### INFECTIOUS DIARRHOEA

- Mild/Moderate/Severe...500mg twice daily, 5 to 7 days

#### TYPHOID FEVER

- Mild/Moderate.....500mg twice daily, 10 days

#### URETHRAL AND CERVICAL

- Uncomplicated Gonococcal infections.....250mg single dose, 1 day

### CHILDREN (1 to 17 YEARS OF AGE)

#### COMPLICATED URINARY TRACT INFECTION OR

- Pyelonephritis...10-20mg/kg twice daily, 10 to 21 days
- Cystic fibrosis.....20mg/kg (max.750mg) twice daily

| PEDIATRIC DOSAGE GUIDELINES                                                      |                                                                                               |             |                |
|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-------------|----------------|
| INFECTION                                                                        | DOSE                                                                                          | FREQUENCY   | USUAL DURATION |
| Complicated Urinary tract or Pyelonephritis (patients from 1 to 17 years of age) | 10 to 20mg/kg (maximum 750 mg per dose, not to be exceeded even in patients weighing > 51 kg) | Twice Daily | 10-21 Days     |
| Inhalational Anthrax (Post-Exposure)                                             | 15 mg/kg (maximum 500 mg per dose)                                                            | Twice Daily | 60 Days        |
| Infectious Diarrhea (Dysentery)                                                  | 10 to 15 mg /kg per dose (maximum 500 mg/dose)                                                | Twice Daily | 5 Days         |
| Typhoid Fever                                                                    | 10 to 15 mg /kg per dose (maximum 500 mg/dose)                                                | Twice Daily | 5 Days         |

#### DURATION OF USE

Duration of treatment depends on severity of the illness and on clinical and biological course OR As directed by the physician.

#### CONTRA-INDICATIONS

Viloc (Ciprofloxacin HCl) is contra-indicated in persons with a history of hypersensitivity to ciprofloxacin HCl or any member of the quinolone class of antimicrobial agents.

#### WARNINGS

There is a risk of serious and occasionally fatal hypersensitivity reactions after multiple doses. Treatment should be discontinued at the first appearance of skin rash, jaundice, or any other sign of hypersensitivity, and supportive measures should be instituted. Risk of Clostridium difficile-associated diarrhoea (CDAD) should be considered.

*Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture. This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug.*

*Selection of a fluoroquinolone for the treatment or prevention of an infection should be limited to those conditions that are proven or strongly suspected to be caused by bacteria.*

#### PREGNANT WOMEN

The safety and effectiveness of ciprofloxacin HCl in pregnant and lactating women have not been established.

#### PAEDIATRICS

Ciprofloxacin HCl should be used in paediatric patients (Less than 18 years of age) only for infections listed in the indications section. An increased incidence of adverse events compared to controls, including events related to joints and/or surrounding tissues, has been observed.

#### PRECAUTIONS

In epileptics and in patients who have suffered from previous CNS-disorders (e.g. Lowered convulsion threshold, previous history of convulsions, reduced cerebral blood flow, altered brain structure or stroke), Viloc should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible central-nervous side effects.

#### SIDE EFFECTS

The symptomatic adverse reactions produced by ciprofloxacin HCl are more or less tolerable and if they become severe, they can be treated symptomatically, these include dizziness, headache, nausea, vomiting, diarrhoea, nervousness, tremors, rashes, urticaria, pruritus, photosensitivity, elevation of liver enzymes, eosinophilia, increased intracranial pressure.

#### DRUG INTERACTIONS

Ciprofloxacin HCl is known to interact with other drugs like aluminium hydroxide and oxide, azlocillin (Na), caffeine, calcium carbonate, chloramphenicol, cyclosporin A, diazepam, foscamet (Na), rifampicin, sucralfate, theophylline, warfarin (Na), alprazolam, bromazepam, zinc sulphate, zolmitriptan, zolpidem (Tartrate), estazolam, ropinrole HCl. These interactions are sometimes beneficial and sometimes may pose threats to life. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

#### DIRECTIONS FOR RECONSTITUTION OF SUSPENSION

##### VILOC DRY POWDER FOR SUSPENSION

**125mg/5ml (15ml) & 250mg/5ml (15ml)**

Tap the bottle several times to loose powder prior to reconstitute. Add a small quantity of boiled & cooled water to the powder in the bottle and shake well, then add water up to the upper mark on the bottle and shake well to make 15ml suspension.

##### VILOC DRY POWDER FOR SUSPENSION

**125mg/5ml (60ml) & 250mg/5ml (60ml)**

Tap the bottle several times to loose powder prior to reconstitute. Add 20ml of previously boiled cool water using enclosed cup and shake well. Again add more 20ml boiled cool water and shake well to make 60ml suspension.

**STABILITY:** See expiry on the pack.

#### PRESENTATION

**Viloc 250mg tablets** Alu-Alu Pack of 10's

**Viloc 500mg tablets** Alu-Alu Pack of 10's

**Viloc Dry powder for suspension (125mg/5ml)** in pack of 60ml bottle

**Viloc Dry powder for suspension (250mg/5ml)** in pack of 60ml bottle

#### INSTRUCTIONS

Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

#### NOTE

When mixed, store in a refrigerator and use within 14 days. Discard any unused portion after 14 days.

**ویلاک** (سپر دفلاکسامن) میلیٹیس ڈرامائی پاؤڈر رائے سسپینشن

**15 ملی لیٹر سسپینشن تیار کرنے کا طریقہ:**

سسپینشن بنانے کے لئے بوتل کو اچھی طرح ہلانیے تاکہ تمام پاؤڈر یکجا ہو جائے۔ بوتل میں تقریباً سا اہلا ہوا بخندرا پانی ڈالیں اور ڈسکن لگا کر اچھی طرح ہلائیں۔ اب بوتل میں اوپر دے کر ڈسکن کے مطابق اہلا ہوا بخندرا پانی ڈالیں اور ڈسکن لگا کر اچھی طرح ہلائیں تاکہ **15 ملی لیٹر سسپینشن** تیار ہو جائے۔

**60 ملی لیٹر سسپینشن تیار کرنے کا طریقہ:**

سسپینشن بنانے کے لئے بوتل کو اچھی طرح ہلانیے تاکہ تمام پاؤڈر یکجا ہو جائے۔ اب ڈبے میں موجود کپ سے تاپ **20 ملی لیٹر پیلے** سے اہلا ہوا بخندرا پانی بوتل میں ڈالیں اور اچھی طرح ہلائیں۔ پھر مزید **20 ملی لیٹر اہلا ہوا بخندرا پانی** ڈالیں اور اچھی طرح ہلائیں تاکہ **60 ملی لیٹر سسپینشن** تیار ہو جائے۔

**نوٹ:** تیار شدہ دوا کو ریفریجریٹر میں رکھیں اور **14 دنوں** کے اندر استعمال کریں۔ باقی ماندہ سسپینشن **14 دنوں** کے بعد استعمال نہ کریں۔

**ہدایات:** دوا کو **30° سینٹی گریڈ** سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ تمام دوا میں بچوں کی پہنچ سے ڈور رکھیں۔ صرف مستعد اکڑ کے لئے پر فرمیت کریں۔



Manufactured by:  
**STANDPHARM PAKISTAN (PVT) LTD.**  
20 Km Ferozepur Road Lahore, Pakistan.

0496-00