

68mm

VIFT

(Ciprofloxacin)

250mg, 500mg Tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film coated tablet contains

Ciprofloxacin as Ciprofloxacin HCl BP...250mg

(Product Spec., BP)

Each film coated tablet contains

Ciprofloxacin as Ciprofloxacin HCl BP...500mg

(Product Spec., BP)

CLINICAL PHARMACOLOGY:**Mechanism of Action:**

Ciprofloxacin is a synthetic 4-quinolone derivative, with bactericidal activity. It acts via inhibition of bacterial DNA gyrase (topoisomerase, which is essential in the reproduction of bacterial DNA), ultimately resulting in interference with DNA function.

Microbiology:

Ciprofloxacin has activity against following microorganisms.

Aerobic Gram-positive microorganisms:

Enterococcus faecalis, Staphylococcus aureus (Methicillin-susceptible strains only), Staphylococcus epidermidis, Staphylococcus saprophyticus, Streptococcus pneumoniae, Streptococcus pyogenes.

Aerobic Gram-negative microorganisms:

Campylobacter jejuni, Citrobacter diversus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Morganella morganii, Neisseria gonorrhoeae, Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, Providencia stuartii, Pseudomonas aeruginosa, Salmonella typhi, Serratia marcescens, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei. Ciprofloxacin has been shown to be active against Bacillus anthracis both in vitro and by use of serum levels as surrogate marker.

PHARMACOKINETICS:

Ciprofloxacin tablet is rapidly and well absorbed from gastrointestinal tract after oral administration. Maximum serum concentrations are attained in 1-2 hours. Plasma protein binding ranges from 20-40%. Ciprofloxacin is widely distributed in the body and tissue penetration is generally good. It appears in the CSF. Ciprofloxacin crosses the placenta and is also distributed in breast milk. High concentrations are achieved in bile. Four metabolites have been identified in human urine which together account for approximately 15% of an oral dose. The metabolites have antimicrobial activity, but are less active than unchanged ciprofloxacin. Ciprofloxacin is an inhibitor of human cytochrome P450 1A2 (CYP1A2) mediated metabolism. The serum elimination half-life is 4 hours. Approximately 40 to 50% of an orally administered dose is excreted in the urine as unchanged drug. Only a small amount of the dose administered is recovered from the bile as unchanged drug. Approximately 20 to 35% of an oral dose is recovered from the feces within 5 days after dosing.

Special Population:**Geriatric Patient:**

Oral plasma concentrations of ciprofloxacin are higher in elderly (> 65 years). Elimination half-life is only slightly (~20%) prolonged in the elderly.

Renal Insufficiency:

In patients with reduced renal function, the half-life of ciprofloxacin is slightly prolonged. Dosage adjustments may be required.

Hepatic Insufficiency:

In patients with stable chronic liver cirrhosis, no significant changes in ciprofloxacin pharmacokinetics have been observed.

INDICATIONS WITH DOSAGE & ADMINISTRATION:

VIFT (Ciprofloxacin) tablets can be taken independent of meal times. Ciprofloxacin should be administered at least 2 hours before or 6 hours after magnesium/aluminum antacids, or sucralfate, didanosine chewable buffered tablets or pediatric powder for oral solution, other highly buffered drugs, or other products containing calcium, iron or zinc.

Adults:

The dosage range for adults is 100-750mg twice daily. The usual duration is 7 to 14 days.

Indications	Daily Dose in mg	Total duration of treatment (potentially including initial parenteral treatment with ciprofloxacin)
Lower respiratory tract Infection		
Upper respiratory tract infection	500mg to 750mg b.i.d	7 - 14 days
Acute exacerbation of chronic sinusitis		
Chronic suppurative otitis media	750mg b.i.d	28 days up to 3 months
Malignant external otitis		
Urinary tract infections	250mg to 500mg b.i.d	3 days
	In pre-menopausal women, 500 mg single dose may be used	
Complicated cystitis, Uncomplicated pyelonephritis	500mg b.i.d	7 days
Complicated pyelonephritis		at least 10 days, continued for longer than 21 days in abscesses
Prostatitis	500mg to 750mg b.i.d	2 to 4 weeks (acute) to 4 to 6 weeks (chronic)
Genital tract infections	500mg OD	1 day (single dose)
Gonococcal urethritis and cervicitis	500mg to 750mg b.i.d	at least 14 days
Epididymo-orchitis and pelvic inflammatory diseases		
Diarrhoea caused by Shigella spp. and empirical treatment of severe travellers' diarrhoea	500 mg b.i.d	1 day
Diarrhoea caused by Shigella dysenteriae type 1		5 days
Diarrhoea caused by Vibrio cholerae		3 days
Typhoid fever		7 days
Intra-abdominal infections due to Gram-negative bacteria	500 mg to 750 mg b.i.d	5 to 14 days

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Infections of the skin and soft tissue		7 - 14 days
Bone and joint infections		max. of 3 months
Neutropenic patients with fever that is suspected to be due to a bacterial infection.	500 mg to 750 mg b.i.d	Therapy should be continued over the entire period of neutropenia
Ciprofloxacin should be co-administered with appropriate antibacterial agent(s) in accordance to official guidance.		
Prophylaxis of invasive infections due to Neisseria meningitidis	500 mg OD	1 day (single dose)
Inhalation anthrax post-exposure prophylaxis and curative treatment	500 mg b.i.d	60 days from the confirmation of Bacillus anthracis exposure

Pediatric population:

Indications	Daily Dose in mg	Total duration of treatment (potentially including initial parenteral treatment with ciprofloxacin)
Cystic fibrosis	20 mg/kg body weight b.i.d with a maximum of 750 mg per dose.	10 - 14 days
Complicated urinary tract infections and pyelonephritis	10 mg/kg body weight b.i.d with a maximum of 750 mg per dose	10 - 21 days
Inhalation anthrax post-exposure prophylaxis and curative treatment	10 mg/kg body weight to 15 mg/kg body weight b.i.d with a maximum of 500 mg per dose	60 days from the confirmation of Bacillus anthracis exposure
Other severe infections	20 mg/kg body weight b.i.d with a maximum of 750 mg per dose.	According to the type of infections

Renal Impaired Patients:

The recommended starting and maintenance doses for patients with impaired renal function is given below:

Creatinine Clearance [ml/min/1.73 m ²]	Serum Creatinine [μmol/L]	Oral Dose (mg)
30 - 60	124 to 168	250-500 mg every 12 h
< 30	> 169	250-500 mg every 24 h
Patients on haemodialysis & Patients on peritoneal dialysis	> 169	250-500 mg every 24 h (after dialysis)
	> 169	250-500 mg every 24 h

Dosing in children with impaired renal and/or hepatic function has not been studied.

CONTRAINDICATIONS:

Ciprofloxacin is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents or any of the product components

Concomitant administration with tizanidine is contraindicated

PRECAUTIONS:**Discontinued VIFT if:**

Experiences pain, inflammation or rupture of a tendon, pseudomembranous colitis is suspected, patient experiences symptoms of neuropathy, hepatic disease(s)

Use VIFT with caution in:

Patients with known or suspected CNS disorders that may predispose to seizures or lower the seizure threshold, patients with known risk factors for prolongation of the QT interval.

to avoid crystalluria patients receiving ciprofloxacin should be well hydrated

to avoid photosensitivity reactions. Patients taking ciprofloxacin should avoid direct exposure to excessive sunlight or UV-light

Pregnancy:

Ciprofloxacin should not be used during pregnancy.

Nursing Mothers:

Ciprofloxacin is excreted in human milk. Use with caution.

DRUG INTERACTIONS:

Cytochrome P450 (CYP450): Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of theophylline, clozapine, tacrine, ropivacaine, tizanidine, duloxetine.

Theophylline: Serious and fatal reactions have been reported when use concomitantly with VIFT. Therefore, serum levels of theophylline should be monitored.

Phenytoin: Phenytoin levels may be altered when ciprofloxacin is used concomitantly.

Warfarin: Ciprofloxacin enhanced the effects of the oral anticoagulant warfarin or its derivatives. Therefore, prothrombin time should be closely monitored.

Probenecid: Probenecid interferes with renal tubular secretion of ciprofloxacin and increase the level of ciprofloxacin in the serum.

Methotrexate: Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin.

NSAIDs: Non-steroidal anti-inflammatory drugs (but not acetyl salicylic acid) in combination of very high doses of quinolones have been shown to provoke convulsions.

Food and Dairy Products: Dairy products or mineral fortified drinks should be avoided with VIFT.

Sildenafil: Cmax and AUC of sildenafil were increased approximately twofold when use with ciprofloxacin.

ADVERSE REACTIONS:

Common: Nausea, Diarrhoea.

Uncommon: Eosinophilia, Anorexia, Agitation, Headache, Dizziness, Sleep disorders, Abdominal disturbances, Elevation of liver enzymes, Rash, Urticaria, Musculoskeletal pain, Renal impairment, Fever.

OVERDOSAGE:

The stomach should be emptied by inducing vomiting or by gastric lavage. The patient should be carefully observed and given supportive treatment, including monitoring of renal function and administration of magnesium, aluminum, or calcium containing antacids which can reduce the absorption of ciprofloxacin.

Adequate hydration must be maintained. Only a small amount of ciprofloxacin (<10%) is removed from the body after hemodialysis or peritoneal dialysis.

INSTRUCTIONS:

Store below 30°C

Protect from light & moisture

Keep out of reach of children

To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:

VIFT (Ciprofloxacin) 250mg Tablets are available in pack size of 10's.

VIFT (Ciprofloxacin) 500mg Tablets are available in pack size of 10's.

Manufactured by:

SIGMA PHARMA International (Pvt.) Ltd.

E-50 North Western Industrial Zone,

Port Qasim Authority, Karachi-Pakistan.

www.sigmapharma.com.pk

خوراک: ڈائری وایت کے مطابق استعمال کریں۔

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