FRONT

BACK

290mm

Rx Ciprofloxacin
Cipromet®

500 mg Film-Coated Tablet
Antibacterial (Quinolone)

FORMULATION:
Each film-coated tablet contains:
Ciprofloxacin (as Hydrochloride), USP.....500 mg

PRODUCT DESCRIPTION:
Ciprofloxacin (Cipromet) 500 mg Film-Coated Tablet is a light pink, round, biconvex, film-coated tablet, bisected on one side.

PHARMACODYNAMICS:
Ciprofloxacin (Cipromet) is a synthetic broad spectrum antibacterial agent.
Ciprofloxacin (Cipromet) is effective in-vitro against virtually all Gram-negative pathogens, including Pseudomonas aeruginosa. It is also effective against Gram-positive pathogens such as Staphylococci and Streptococci. Anaerobes are generally less susceptible.

Ciprofloxacin has a rapid bactericidal action, not only in the proliferation phase but also in the resting phase.

During the proliferation phase of a bacterium, a segmental twisting and untwisting of the chromosomes take place. An enzyme called DNA gyrase plays a decisive part in this process. Ciprofloxacin inhibits this DNA gyrase in a way that arrests the bacterial metabolism since vital information can no longer be read from the bacterial chromosome.

Resistance to Ciprofloxacin develops slowly and in stages (multiple-step type).

Plasmid-mediated resistance development of the kind that occurs with B-lactam antibiotics, aminoglycosides, and tetracyclines has not been observed with Ciprofloxacin. It is of clinical interest that plasmid-carrying bacteria are also completely sensitive to Ciprofloxacin.

On account of its special mode of action, Ciprofloxacin does not suffer from general parallel resistance to other important, chemically different active substance groups, such as B-lactam antibiotics, tetracyclines, macrolides or peptide antibiotics, sulphonamides, trimethoprim or nitrofuran derivatives, and aminoglycosides. In its indication area, Ciprofloxacin remains completely effective on pathogens resistant to the above-mentioned groups of antibiotics.

Parallel resistance is observed within the group of gyrase inhibitors. However, because of the high primary sensitivity to Ciprofloxacin shown by most organisms, parallel resistance is less pronounced with this drug. Ciprofloxacin is thus; often still effective on pathogens that are already resistant to the less effective gyrase inhibitors.

Because of its chemical structure, Ciprofloxacin is completely effective on B-lactamase forming bacteria.

Ciprofloxacin can be used in combination with another antibiotic. In vitro studies with usually sensitive-pathogens, carried out using Ciprofloxacin in combination with B-lactam antibiotics and aminoglycosides, have shown primarily additive or indifferent effects. Synergistic increases in efficacy were relatively rare and antagonistic effects are very rare.

Possible combination with drugs include:
For Pseudomonas: azlocillin, ceftazidime
For Streptococci: mezlocillin, azlocillin, other effective B-lactam antibiotics
For Staphylococci: B-lactam antibiotics, particularly isoxazolyl penicillins, vancomycin
For Anaerobes: metronidazole, clindamycin

PHARMACOKINETICS:
Ciprofloxacin given as an oral tablet is rapidly and well-absorbed from the gastrointestinal tract after oral administration. The absolute bioavailability is approximately 70% with no substantial loss by first pass metabolism. Maximum serum concentrations are attained 1 to 2 hours after oral dosing. The binding of Ciprofloxacin to serum proteins is 20% to 40% which is not high enough to cause significant protein binding interactions with other drugs. Four metabolites have been identified in urine which account for approximately 15% of an oral dose. The metabolites have antimicrobial activity, but are less active than unchanged Ciprofloxacin. The elimination half-life in patients with normal renal function is approximately 4 hours. Approximately 40% to 50% of an oral dose is excreted in the urine as unchanged drug.

INDICATIONS:
Uncomplicated and Complicated Infections caused by Ciprofloxacin Sensitive pathogens
Infections of the kidneys and/or urinary tract
Infections of the respiratory tract
Infections of the abdominal cavity (e.g., Infections of the GI tract or of the biliary tract, peritonitis)
Infectious diarrhea & typhoid fever
Infections of the genital organs, including adnexitis, gonorrhea, prostatitis
Infection of the middle ear (otitis media), of the paranasal sinuses (sinusitis) especially if these are caused by gram-negative organisms including Pseudomonas or by gram-positive pathogens including Staphylococcus.
Infection of the eyes
Infections of the bones and joints
Infections of the skin and soft tissue
Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g., patients on immunosuppressants or have neutropenia)

SEPSIS:
Infections or imminent risk of infection (prophylaxis) in patients whose immune system has been weakened (e.g., patients on immunosuppressants or have neutropenia.)
Selective Intestinal decontamination in immunosuppressed patients.
According to in-vitro investigations, the following pathogens can be regarded as sensitive:
E. coli, Shigella, Salmonella, Citrobacter; Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative), Providencia, Morganella,Yersinia,Vibrio, Aeromonas, Plesiomonas, Pasteurella, Haemophillus, Staphylococcus, Listeria, Corynebacterium, Chlamydia.
The following show varying degrees of sensitivity:
Gardnerella, Flavobacterium, Alcalagines, Streptococcus agalactiae, Enterococcus faecalis, Streptococcus pyogenes, Streptococcus pneumonia, Viridans group streptococci, Mycoplasma hominis, Mycobacterium tuberculosis, and Mycobacterium fortuitum. With a few exceptions anaerobes are moderately sensitive (e.g., Peptococcus, Peptostreptococcus) to resistant (e.g., Bacteroides).
CIPROFLOXACIN is ineffective against Treponema pallidum.

DOSAGE AND ADMINISTRATION:
Ciprofloxacin (Cipromet) is generally administered in oral doses of 250 mg - 500 mg BID for most indications for 5-7 days.
Infections of the kidneys, urinary tract & abdominal cavity:
-Mild to moderate: 250 mg twice daily
-Severe complicated: 500 mg twice daily
Infections of the respiratory tract, bone & joint, skin & skin structures:
-Mild to moderate: 500 mg twice daily
-Severe complicated: 750 mg twice daily
Infectious diarrhea & typhoid fever: 500mg twice daily
Infections of the middle ear (otitis media), paranasal sinuses (sinusitis): 500 mg twice daily
Bacterial prostatitis: 500 mg twice daily
Uncomplicated urethral & cervical gonococcal infections: single 250 mg dose is recommended.
Elderly patients should receive a dose as low as possible depending on the severity of their illness and creatinine clearance.

Method of Administration:
The tablet is swallowed whole with a small amount of fluid. It can be taken independent of meal times, (if the tablet is taken on an empty stomach, the active substance is absorbed more rapidly).

DURATION OF TREATMENT:
The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. It is essential to continue therapy for at least 3 days after disappearance of the fever or of the clinical symptoms. Mean duration of treatment:
-up to 7 days for infections of the kidneys, urinary tract, and abdominal cavity
-1 day for acute uncomplicated gonorrhea and cystitis
-over the entire period of neutropenic phase in patients with weakened body defenses
-a maximum of 2 months in osteomyelitis
-7 to 14 days in all other infections

In Streptococcal infections, the treatment must last at least 10 days, because of the risk of late complications. Infections caused by Chlamydia should also be treated for a minimum of 10 days. Or as prescribed by the physician.

OVERDOSE AND TREATMENT:
In the event of acute, excessive oral overdose, reversible renal toxicity has been reported in some cases. Therefore, apart from routine emergency measures, it is recommended to monitor renal function and to administer Mg or Ca containing antacids, which reduce the absorption of Ciprofloxacin.
Only a small amount of Ciprofloxacin (<10%) is removed from the body after hemodialysis or peritoneal dialysis.

CONTRAINDICATIONS:
Ciprofloxacin must not be used in cases of hypersensitivity to Ciprofloxacin or other quinolone chemotherapeutics.
Ciprofloxacin must not be prescribed for children, adolescents, pregnant women and nursing mothers, since there is no experience on the drug's safety in these patient groups and since, on the basis of animal studies, it is not entirely improbable that the drug cause damage to articular cartillage in the immature organism.

SPECIAL WARNINGS & PRECAUTIONS FOR USE

Ciprofloxacin should not be used in patients at increased risk unless there are no other treatment available. Patients at increased risk include those with a history of blockages or aneurysm (abnormal bulges) of the aorta or other blood vessel, high blood pressure, certain genetic disorders involving blood vessels (i.e., Marfan syndrome and Ehlers-Danlos syndrome), and the elderly. Fluoroquinolones can increase the occurrence of serious aortic ruptures which may result to hemorrhage or death. Patients should seek immediate medical treatment for any symptoms associated with aortic aneurysm i.e., throbbing pain in the stomach area, deep pain in back or side of the stomach, pain in the jaw, neck, back or chest, coughing or hoarseness and shortness of breath, trouble breathing or swallowing. Stop fluoroquinolone treatment immediately if a patient reports side effect suggestive of aortic aneurysm or dissection.

Gastrointestinal System
In the event of severe and persistent diarrhea during or after treatment, a physician must be consulted, since this symptom can hide a serious intestinal disease (life threatening pseudomembranous colitis with possible fatal outcome), requiring immediate treatment. In such cases, Ciprofloxacin must be discontinued and appropriate therapy initiated. Drugs that inhibit peristalsis are contraindicated. There can be a temporary increase in transaminases, alkaline phosphates or cholestatic jaundice, especially in patients with previous liver damage.

Nervous System
In epileptics and in patients who have suffered from previous CNS-disorders (e.g., lowered convulsion threshold, previous history of convulsion, reduced cerebral blood flow, altered brain structure or stroke), Ciprofloxacin should only be used when the benefits of treatment exceed the risks, since these patients are endangered because of possible central - nervous adverse effects.
In some instances, the CNS reactions occurred after the first administration of Ciprofloxacin already. In rare cases, depression or psychosis can progress to self-endangering behavior. In these cases, Ciprofloxacin has to be discontinued and the physician should be informed immediately.

Hypersensitivity
In some instances, the hypersensitivity and allergic reactions already occurred after the first administration and in very rare instances anaphylactic/anaphylactoid reactions can progress to a life threatening shock. In these cases, Ciprofloxacin has to be discontinued and the physician must be immediately notified.

Musculoskeletal System
At any sign of tendonitis (e.g., painful swelling) the administration of Ciprofloxacin should be discontinued, physical exercise should be avoided, and a physician should be consulted.
Tendon rupture (predominantly achilles tendon) has been reported predominantly in the elderly on prior treatment with glucocorticoids.

Skin and Appendages
Ciprofloxacin has been shown to produce photosensitivity reactions. Patients taking Ciprofloxacin should avoid direct exposure to excessive sunlight or UV-light. Therapy should be discontinued if photosensitization (i.e., Sunburn-like reactions) occurs.

Ability to drive and use of machines
Even when the drug is taken exactly as prescribed, it can affect the speed of reactions to such an extent that the ability to drive or to operate machines is impaired. This applies particularly in combination with alcohol.

PREGNANCY AND LACTATION:
Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Ciprofloxacin should not be used during pregnancy unless the potential benefit justifies the potential risk to both fetus and mother.
Ciprofloxacin is excreted in human milk. The amount of Ciprofloxacin absorbed by the nursing infant is unknown. Because of the potential for serious adverse reactions in infants nursing from mothers taking Ciprofloxacin, a decision should be made whether to discontinue breastfeeding or to discontinue the drug, taking into account the importance of the drug to the mother.

INTERACTIONS
The simultaneous administration of oral Ciprofloxacin and iron, sucralfate or antacids and highly buffered drugs (e.g., Antiretrovirals), containing magnesium, aluminum, or calcium reduce the absorption of Ciprofloxacin. Consequently, Ciprofloxacin should be administered either 1-2 hours before, or at least 4 hours after these preparations.
This restriction does not apply to antacids belonging to the class of H2 receptor blockers. Concurrent administration of Ciprofloxacin and theophylline can cause an undesirable increase in the serum theophylline concentration. This can lead to theophylline-induced side effects; in very rare cases, these side effects can be life threatening or fatal. If concurrent use of the two products is unavoidable, the serum theophylline concentration should therefore be checked and the theophylline dose appropriately reduced.

Animal studies have shown that the combination of very high doses of quinolones (gyrase inhibitors) and certain non-steroidal anti-inflammatory agents (but not acetyl salicylic acid) can provoke convulsions. A transient rise in the concentration of serum creatinine was observed when Ciprofloxacin and cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).

The simultaneous administration of Ciprofloxacin and warfarin may intensify the action of warfarin.
In particular cases, concurrent administration of Ciprofloxacin and glibenclamide can intensify the action of glibenclamide (hypoglycaemia).
Probenecid interferes with renal secretion of Ciprofloxacin. Co-administration of probenecid and Ciprofloxacin increases the Ciprofloxacin serum concentrations.

Metoclopramide accelerates the absorption of Ciprofloxacin (oral) resulting in a shorter time to reach maximum plasma concentrations. No effect was seen on the bioavailability of Ciprofloxacin.

ADVERSE REACTIONS:
Nausea, diarrhea, vomiting, abdominal discomfort, headache, restlessness and rash.

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.
Keep drugs out of reach of children.

Ciprofloxacin (Cipromet) tablets must not be used after the expiry date.

Reg. No.: DRP - 1359
Date of First Authorization: 30 MAY 2005
Date of Revision of Package Insert: JANUARY 2024

AVAILABILITY:
500 mg Film Coated Tablet
Alu-Clear PVC Blister Pack x10's (Box of 50's)

MANUFACTURED BY:
HIZON LABORATORIES, INC.
Assumption Road, Sumulong Highway,
Antipolo City

EXCLUSIVELY DISTRIBUTED BY:
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