Cipronat®

ciprofloxacine

INDICATIONS AND DOSAGE

INFECTION	SEVERITY	DOSE	FREQUENCE	NORMAL DURATION
Urinary tract infections (cystitis / pyelonephritis)	Acute - uncomplicated	100 mg to 250 mg	12 hours	3 days
	Simple / moderate	250 mg	12 hours	7 - 14 days
	Severe / complicated	500 mg	12 hours	7 - 14 days
Prostatitis	Simple / moderate	500 mg	12 hours	28 days
Lower respiratory infections	Simple / moderate	500 mg	12 hours	7 - 14 days
	Severe / complicated	750 mg	12 hours	7 - 14 days
Upper respiratory infections	Simple / moderate	500 mg	12 hours	10 days
Infections of skin and soft tissue	Simple / moderate	500 mg	12 hours	7 - 14 days
	Severe / complicated	750 mg	12 hours	7 - 14 days
Osteo-articular infections	Simple / moderate	500 mg	12 hours	≥ 4 to 6 wks
	Severe / complicated	750 mg	12 hours	≥ 4 to 6 wks
Gastrointestinal infections Intra-abdominal infections		500 mg to 750 mg	12 hours	7 - 14 days
Infectious diarrhea		500 mg	12 hours	7 - 14 days
Typhoid fever		500 mg	12 hours	10 days
Genital tract infections (rethritis and gonococcal cervicitis / orchi epididymitis and gynecological infections)		250 mg	Single dose	
The dosage depends on the indication, the severity and the site of infection, the sensitivity of the causative germ(s), the patient's renal function and weight of the child and adolescent.				

ADVANTAGES AND KEY POINTS

- **CIPRONAT®** is a synthetic fluoroquinolone antibiotic with bactericidal action which exhibits antibacterial activity against the majority of gram-positive and gram-negative pathogens.
- **CIPRONAT®** is at your disposal:
  - In three dosages for oral administration: 250mg, 500mg and 750mg.
  - In packs of 14 tablets, avoiding spillage.
- **CIPRONAT®** is not recommended for children and adolescents (5-17 years), but if considered essential, an oral dose range from 7.5 – 15 mg per kg body weight daily should be used*.
- **CIPRONAT®** combines the bactericide power of ciprofloxacine with the quality from Dafra: manufactured in Europe according to European GMP and at an affordable price.

(*) Prescribing information Cipronat, Dafra Pharma (2008)

DAFRA PHARMA INTERNATIONAL

Bureau Central
Slachthuisstraat 30/7
2300 Turnhout – Belgium

3FICIPE 2021

Dafra PHARMA

Setting the Standard

www.dafrapharma.com

Cipronat®

ciprofloxacine

EUROPEAN GMP

THE POWER OF CIPROFLOXACINE
COMBINED WITH THE DAFRA QUALITY

BOX OF 14 TABLETS
FOR A COMPLETE TREATMENT

Dafra PHARMA

Setting the Standard

www.dafrapharma.com

Cipronat®

ciprofloxacine

PRESENTATIONS

CIPRONAT® 250
2 Blisters of 7 film-coated tablets ciprofloxacine 250 mg
CIPRONAT® 500
2 Blisters of 7 film-coated tablets ciprofloxacine 500 mg
CIPRONAT® 750
2 Blisters of 7 film-coated tablets ciprofloxacine 750 mg

THERAPEUTIC INDICATIONS

Acute sinusitis; lower respiratory tract infections: pneumonia, cysticfibrosis and acute exacerbations of chronic bronchitis (although it has been found to be effective in clinical studies ciprofloxacin is not the drug of first choice in the treatment of pneumonia); urinary tract infections: acute uncomplicated cystitis in women, chronic bacterial prostatitis; uncomplicated intra-abdominal infections (in combination with metronidazole when appropriate): cholecystitis, peritonitis, appendicitis, cholangitis, wound, abscess and fistulas; skin and skin-structure infections: pyodermitis, wound infections, abscesses, cellulites, lymphangitis; bone and joint infections: osteomyelitis and septic arthritis; infectious diarrhea; typhoid fever (eradication of typhoid bacilli in typhoid carriers by ciprofloxacin has not been proven); uncomplicated cervical and urethral gonorrhoea.

POSOLOGY AND METHOD OF ADMINISTRATION

In **adults**, for the treatment of mild to moderate infections 500 mg every 12 hours, for severe infections 750 mg every 12 hours is recommended. Uncomplicated urinary tract infections can be treated with 250 mg every 12 hours. The duration of treatment depends upon the severity of infection. The usual duration is 7 to 14 days. Tablets should be administered orally.
Ciprofloxacin should be administered at least 2 hours before of 6 hours after magnesium/ aluminium antacids, or sucralfate, Videx® (didanosine) chewable/ buffered tablets of pediatric powder for oral solution, or other products containing calcium, iron or zinc. In **elderly patients** and persons with reduced kidney function, the dosage may be adjusted. For **children and adolescents (5-17 years) CIPRONAT®** is not recommended, but if considered essential, oral dose ranges from 7.5 – 15 mg per kg body weight daily should be used.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

As with all quinolones, ciprofloxacin should be used with caution in the presence of central nervous system disorders or risk factors associated with an increase tendency to convulsions or decreased convulsive threshold (e.g. severe cerebral atherosclerosis, epilepsy, some drug therapies and renal failure). In patients undergoing therapy with quinolone, including ciprofloxacin, convulsions, intracranial pressure elevation and toxic psychosis have been reported. Quinolones and ciprofloxacin may cause symptoms related to the central nervous system such as nervousness, agitation, insomnia, anxiety, nightmares and paranoia. Ciprofloxacin is not effective in the treatment of syphilis. If ciprofloxacin is administered in high doses for treating gonorrhoea, symptoms of syphilis may be masked. In patients treated with ciprofloxacin for gonorrhoea serologic tests for syphilis should be obtained at three months after the end of treatment. Ciprofloxacin may cause crystalluria in alkaline urine. Patients should be advised to drink liberal amounts of water

and alkalinization of urine should be avoided. In patients with impaired renal function dose adjustment is necessary. Photosensitivity reactions have been reported in patients receiving quinolone compounds. Patients receiving ciprofloxacin should avoid direct sunlight or artificial UV radiation. If symptoms of phototoxicity occur, the drug should be discontinued. During longterm ciprofloxacin administration renal, hepatic and hematopoetic functions should be assessed periodically.

INTERACTIONS

Serious and fatal reactions have been reported in patients receiving ciproploxacin in combination with theophylline. Concurrent administration of ciprofloxacin with teophylline may lead to elevated serum concentrations of teophylline and increased risk of teophylline toxicity. Antacids containing magnesium, aluminum, or calcium, sucralfate, divalent or trivalent cations such as iron and zinc may interfere with the absorption of ciprofloxacin resulting in reduced blood levels. Concurrent use of ciprofloxacin with phenytoin may result in altered phenytoin blood levels. Quinolones may enhance the effect of oral anticoagulants, including warfarin and its derivative. Prothrombin time or other coagulation tests should be monitored closely in patients receiving both drugs concomitantly.

UNDESIRABLE EFFECTS

Most of these side effects were light to moderate in severity and disappeared after discontinuation of the drug. These symptoms may appear following the first dose, if these reactions occur during ciprofloxacin therapy, the drug should be discontinued and appropriate therapy should be instituted.

OVERDOSE

In the event of acute overdosage, stomach is evacuated by inducing emesis or by gastric lavage. The patient should be carefully observed and supportive and symptomatic treatment is applied when necessary. Maintenance of adequate hydration is essential. Only about 10 % of ciprofloxacin can be removed from the body by the application of hemodialysis or peritoneal dialysis.

PHARMACOLOGICAL PROPERTIES

Ciprofloxacin is a fluoroquinolone antibiotic with bactericidal action which exhibits antibacterial activity against the majority of gram-positive and gram-negative pathogens. Ciprofloxacin is absorbed rapidly and well by the oral route. Its absolute bioavailability is approximately 70%. Peak plasma concentrations are reached in 1 to 2 hours after an administered dose. When administered with food Cmax is delayed but total absorption does not change. Plasma half-life is approximately 4 hours.

PHARMACOKINETIC PROPERTIES

Ciprofloxacin is orally well absorbed, its bioavailability is approximately 70%. Peak plasma concentrations are reached 1-2 hours after dosing. Ciprofloxacin spreads well in body tissues and fluids.
Tissue concentrations in particular at the genitalia and prostate are higher than the plasma levels. The half-life of ciprofloxacin is about 4 hours. Protein binding is 20 to 40%.
Approximately 40 to 50% of the administered dose is eliminated unchanged in the urine and 15% as metabolites.

CONSERVATION

Store below 25°C, in the original package, protected from humidity. Keep out of reach and sight of children.

RANGE OF ACTION

Ciprofloxacin is an antibiotic with broad spectrum covering, among others, the Enterobacteriaceae. Specifically, **CIPRONAT®** is active on the followig germs: Salmonella, Shigella, Enterobacter, Klebsilla, Citrobacter, Escherichia coli, Serratia, Proteus, Streptococcus, Gonorrhoea, Legionella, Staphylococcus meti-S, Pseudomonas.

BLOOD CONCENTRATION

Tmax: 1 to 2 hours - Cmax: 3 mg / l

For the complete SMPC, please consult www.dafrapharma.com