سپرول® گولیاں

سپروفلوکساسین ہائیڈروکلورائیڈ یو۔ایس۔پی

وسیع العمل اور طاقتور اینٹی بائیوٹک

خوراک: (بالغان)

* عام طور پر زیادہ انفیکشن میں ۲۵۰ سے ۷۵۰ ملی گرام دن میں دو مرتبہ ۷ سے ۱۴ دن کے لیے۔
* ہڈیوں اور پروسٹاٹیس کی شدید یا پرانی انفیکشن میں ۵۰۰ ملی گرام دن میں دو مرتبہ ۴ سے ۶ ہفتہ کیلئے۔
* عام انفیکشن میں ۲۵۰ ملی گرام دن میں دو مرتبہ۔
* پیشاب کے نظام میں پیچیدہ انفیکشن میں ۲۵۰ سے ۵۰۰ ملی گرام دن میں دو مرتبہ۔
* سوزاک کے لیے ۲۵۰ یا ۵۰۰ ملی گرام ایک ہی خوراک کی صورت میں۔
* نظام تنفس کی انفیکشن میں ۲۵۰ سے ۵۰۰ ملی گرام دن میں دو مرتبہ۔
* پیچش میں ۵۰۰ ملی گرام دن میں دو مرتبہ۔
* حد درجہ انفیکشن میں ۷۵۰ ملی گرام دن میں دو مرتبہ۔
* سرجری میں انفیکشن سے بچاؤ کیلئے ۷۵۰ ملی گرام کی ایک خوراک آپریشن سے ۱½ گھنٹہ پہلے۔

احتیاط:

گردے اور جگر کی محدود کارکردگی کی صورت میں کریٹینائن کا نکاس <۲۰ ملی لیٹر/منٹ سیرم کریٹینائن >۳ ملی گرام/۱۰۰ ملی لیٹر کے حساب سے ممکنہ حد تک سپروفلوکساسین کے خون میں ارتکاز کی سطح کو جانچنا ضروری ہے۔

ممانعت:

سپروفلوکساسین کے کری ہڈی پر ضرر رساں اثرات کے امکانات کی وجہ سے بچوں، بڑھتے ہوئے نونہالوں، حاملہ اور دودھ پلانے والی عورتوں میں تجویز نہیں کرنی چاہیے۔ تاہم بچوں میں ناگزیر حالات میں ۵۔۷ ملی گرام سے ۱۵ ملی گرام فی کلوگرام بلحاظ وزن دن میں دو مرتبہ تک دے سکتے ہیں۔

ہدایات:
* ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
* دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
* دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
* تمام دوائیں بچوں کی پہنچ سے دُور رکھیں۔

پیشکش: سپرول۔۲۵۰ فلم کوٹڈ گولیاں (۱×۱۰) بلسٹر پیک میں دستیاب ہیں۔
سپرول۔۔۵۰۰ فلم کوٹڈ گولیاں (۱×۱۰) بلسٹر پیک میں دستیاب ہیں۔

Manufactured by:
Schazoo Zaka (Pvt) Ltd.
Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhupura, Pakistan.

Ciprol® TABLETS

Ciprofloxacin Hydrochloride U.S.P.

Broad spectrum high performance DNA-gyrase inhibitor

COMPOSITION:
Each film coated tablet contains:
Ciprofloxacin (as HCl) U.S.P. ..... 250 mg.
Ciprofloxacin (as HCl) U.S.P. ..... 500 mg.

CLINICAL PHARMACOLOGY:
Ciprofloxacin is a broad spectrum DNA-gyrase inhibitor, a fourth generation fluoroquinolone derivative having strong bactericidal activity against variety of multi-resistant gram-positive and gram-negative pathogens including penicillin and methicillin resistant strains. The absolute bioavailability is 70-80% and high attainable concentrations at the target site i.e. tissues and body fluids within 1-1.5 hours after oral administration of single dose. The elimination half life is approximately 4 hours, 40-50 % is excreted in urine unchanged with renal clearance 300 ml/min., 1-2 % in bile as metabolites & 20-35 % is recovered in feces within 5 days. In susceptible micro-organisms it prevents bacterial chromosomal transcription by inhibiting a critical enzyme catalyst DNA-gyrase resulting in a total "Black-out" in bacterial cell chemistry, metabolic cessation with rapid decrease in bacterial growth and multiplication processes.

ANTI-MICROBIAL ACTIVITY:
Ciprofloxacin has strong in-vitro activity against most strains of gram-negative and gram-positive aerobic and anaerobic bacteria. Due to specific mode of action it does not generally exhibit parallel resistance to any other group of antibiotics for instance penicillins, cephalosporins, aminoglycosides and tetracyclines etc. Therefore, Ciprofloxacin is highly effective against bacteria resistant to these drugs and against the following micro-organisms;

Gram-negative

Aeromonas spp.	Acinetobacter spp.	Branhamella catarrhalis
Campylobacter coli	Campylobacter jejuni	Chlamydia spp.
Citrobacter spp.	Edwardsiella tarda	Enterobacter spp.
Escherichia coli	Haemophilus spp.	Hafnia alvei
Klebsiella spp.	Legionella spp.	Moraxella spp.
Morganella morganii	Neisseria spp.	Pasturella multocida
Plesiomonas shigelloides	Proteus spp. (indole+)	Providencia spp.
Pseudomonas aeruginosa	Salmonella spp.	Serratia spp.
Shigella spp.	Vibrio spp.	Yersinia spp.

Gram-positive

Brucella melitensis	Corynebacterium spp.	Listeria monocytogenes
Staphylococcus spp.	Streptococcus agalactiae	

The following micro-organisms are sensitive in varying degree;

Gram-negative

Alcaligenes spp.	Flavobacterium spp.	Gardnerella spp.
Mycobacterium fortuitum	Mycobacterium tuberculosis	Mycoplasma hominis

Gram-positive

Streptococcus faecalis	Streptococcus pneumonia	Streptococcus pyogenes
Streptococcus viridans		

INDICATIONS:
Ciprol is indicated in acute, chronic and recurrent infections caused by the susceptible strains of micro-organisms in the following pathological conditions;
Severe systemic infections --- Septicaemia, bacteraemia, peritonitis, infections or imminent risk of infections in immunocompromised patients with neutropenia or solid tumours and with selective intestinal decontamination in patients treated with immunosupressants and in infected burn cases.
Respiratory tract infections--- Lobar and bronchopneumonia, acute and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyma and as an advisable treatment for gram-negative pneumonia.
Ear, nose and throat infections --- Otitis media, sinusitis and mastoiditis especially if these are caused by gram-negative bacteria including *Pseudomonas aeruginosa* and *Staphylococcus aureas*.
Urinary tract infections --- Uncomplicated and complicated urethritis, cystitis, polynephritis, prostatitis and epididymitis.
Skin and soft tissues infections --- Infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas and infected burns.
Gastro-intestinal infections --- Enteric fever, infectious diarrhoea and as prophylactic against infection in elective upper gastro-intestinal surgery and endoscopic procedures where there is an increased risk of infection.
Eye --- Corneal ulcers and bacterial conjunctivitis.
Biliary tract infections --- Cholangitis, cholecystitis and empyma of gall bladder.
Abdominal cavity infection --- Peritonitis and intra-abdominal abscesses.
Bones and joint infections --- Osteomyelitis and septic arthritis.
Pelvic infections --- Salpingitis, endometritis and pelvic inflammatory disease.
Reproductive organ infection --- Gonorrhoea including urethral, rectal and pharyngeal gonorrhoea caused by β-lactamase producing micro-organisms or organisms moderately sensitive to penicillin.

DOSAGE AND ADMINISTRATION:
The dosage is determined by the severity and type of infection, the sensitivity of the causative agent(s) and the age, weight and renal function of the patient. Where as the duration of treatment depends upon severity of infection, clinical response and bacteriological findings. The tablets should be taken with fresh water, preferably on an empty stomach.
Adults:
The dosage range for adults in majority of infections is 250-750 mg twice daily for 7-14 days.
In acute & chronic osteomyelitis & prostatitis 500 mg twice a day for 4-6 weeks & should be treated at least 3 days after the signs & symptoms have disappeared.
In gonorrhoea, a single dose of 250 mg or 500 mg.
In acute, uncomplicated cystitis, 250 mg twice daily.
In infections of lower and upper urinary tract 250-500 mg twice daily.
In respiratory tract infections, 250-750 mg twice daily.
In infected diarrhoea, 500 mg twice daily.
In cystic fibrosis, 750 mg twice daily.
In surgical prophylaxis, a single dose of 750 mg 60-90 minutes prior to surgery.
Impaired renal function in patients with serum creatinine > 3 mg/100 ml and creatinine clearance < 20 ml/minute the dosage adjustment may be achieved by reducing the total daily dose by half.
Elderly : Patients should receive as low a dose as possible, taking into account the severity of the illness and the rate of creatinine clearance.
Adolescents and children: Due to risk of arthropathy the use of ciprofloxacin in children and growing adolescents is not recommended. However, where the benefit of using ciprofloxacin is considered to outweigh this potential risk, the dosage should be 7.5-15 mg/Kg/day depending upon the severity of infection, administered twice daily.

CONTRA-INDICATIONS:
The use of **Ciprol** is contra-indicated in patients with;
– A history of hypersensitivity to ciprofloxacin or other quinolone derivatives.
– Epilepsy or prone to convulsive seizure or other central nervous system complications including pre-existing central nervous system (CNS) lesions involving a lowered seizure threshold, after cerebro-cranial injuries, reduced cerebral blood flow due to severe cerebral arteriosclerosis, altered brain structure, stroke, inflammation or other factors which predispose to seizures.
– In children and growing adolescents except where the benefits of treatment exceed the risk.

PRECAUTIONS:
– Ciprofloxacin can impair patient's ability to drive or operate machinery, particularly in conjunction with alcohol.
– Ciprofloxacin therapy requires well hydration and less alkalinity of the urine to avoid any possibility of crystalluria.
– Ciprofloxacin should be administered in combination with an appropriate antibiotic effective against anaerobes in case of suspected gastro-oesophageal obstructive lesions.
– Ciprofloxacin or quinolones should be used with caution in patients genetically defficient in glucose-6-phosphate dehydrogenase which may lead to haemolytic reactions.
– Ciprofloxacin has been shown to cause arthropathy in immature animals and therefore its use during pregnancy and lactation is not recommended.

DRUG INTERACTIONS:
– Concurrent use of antacids containing magnesium or aluminium and iron therapy may interfere with the absorption of ciprofloxacin, resulting in serum and urine levels lower than the desired level.
– Ciprofloxacin may potentiate the effect of bronchodilator theophylline by elevation of plasma concentrations when administered concomitantly.
– Ciprofloxacin may prolong the bleeding time by augmenting the effect of anticoagulants.
– Simultaneous administration of quinolones and anti-diabetics may accentuate the hypoglycaemic effect of glibenclamide.
– Probenecid interferes with the renal tubular absorption of ciprofloxacin and produces an increase in the level of ciprofloxacin in serum.
– Concomitant use of ciprofloxacin and cyclosporin may lead to an increase in serum creatinine level.
– Animal study demonstrates that high doses of ciprofloxacin in combination with some non-steroidal anti-inflammatory drugs e.g. fenbufen but not acetylsalicylic acid can lead to convulsions.
– Opiate or regional anaesthetic agents are not administered concomitantly with ciprofloxacin when used for surgical prophylaxis.
– Prolonged use of ciprofloxacin may result in superinfections. Therefore, monitoring of patient condition and microbial susceptibility testing is essential during therapy.

SIDE EFFECTS:
Ciprofloxacin is generally well tolerated. The most frequently reported adverse reactions;
GIT disturbances --- Nausea, vomiting, dyspepsia, diarrhoea, abdominal pain, anorexia, flatulence, dysphagia. Rarely pseudomembranous colitis.
CNS disturbances ---Headache, restlessness, dizziness, tremor, convulsions, confusion, hallucinations, somnolence, depression. Very rarely sleep disorders, anxiety and rise in intracranial vault pressure.
CVS disturbances ---Eosinophilia, leucopenia, thrombocytopenia, thrombocytosis, altered prothrombin level and tachycardia.
Skin disorders ---Rash, pruritus, urticaria, photosensitivity, drug induced fever, anaphylactoid reactions. Very rarely petechiae, haemorrhagic bullae, vasculitis, Stevens-Johnson and Lyell Syndrome.
Hepatic disturbances ---Transient increase in liver enzymes or serum billirubin (particularly in patients with previous liver damage), hepatitis, jaundice and hepatic necrosis.
Renal disturbances ---Transient increase in blood urea or serum creatinine, renal failure, crystalluria and nephritis.
Musculoskeletal disturbances ---Arthralgia, myalgia and rarely tenosynovitis.
Special sense disturbances ---Very rarely, visual disturbances, impaired taste and smell, tinnitus and transient impairement of hearing at high frequencies.

OVER DOSAGE:
Gastric lavage should be performed as soon as possible after ingestion of tablets. The serum levels of ciprofloxacin are reduced by dialysis.

STORAGE CONDITIONS:
* Protect from heat, light and moisture. * Store in a cool and dry place.
* Keep all medicines out of the reach of children.

PACKING :
Ciprol 250 mg film coated tablets are available in (1x10) blister pack.
Ciprol 500 mg film coated tablets are available in (1x10) blister pack.