EURO®
(Ciprofloxacin)

یورو®
(سپروفلاکساسن)

COMPOSITION:
EURO® **250 mg Tablets:**
Each tablet contains
Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin ..... 250 mg

EURO® **500 mg Tablets:**
Each tablet contains
Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin ..... 500 mg

DESCRIPTION:
The active ingredient of EURO® 250 mg Tablets and EURO® 500 mg Tablets is Ciprofloxacin Hydrochloride USP. Ciprofloxacin, a fluoroquinolone, is an extremely broad spectrum antimicrobial agent and acts by inhibiting a subunit of DNA gyrase which is essential in the reproduction of bacterial DNA. This mode of action differs from that of Penicillins, Cephalosporins, Aminoglycosides and Tetracyclines and therefore, organisms resistant to these antibiotics are generally sensitive to Ciprofloxacin.

PHARMACOLOGICAL PROPERTIES:
PHARMACODYNAMICS
EURO® (Ciprofloxacin) is a broad spectrum antimicrobial preparation from fluoroquinolone. It inhibits bacterial DNA gyrase, what leads to blocking of replication of DNA and synthesis of proteins. It acts as bactericidal agent both in relation to the growing microorganisms and microorganism in resting phase. It is active in relation to gram- negative and gram-positive bacteria. The development of parallel resistance to other antibiotics (not belonging to gyrase inhibitors) doesn't happen at the application of EURO® (Ciprofloxacin). It makes the preparation highly efficient in relation to bacteria resistant to other antibiotics.

PHARMACOKINETICS
After the intake, ciprofloxacin is quickly absorbed from gastrointestinal tract. The bioavailability of the preparation makes 50-85%. The plasma protein binding is 30%. It penetrates through the placental barrier. It eliminates predominantly via urine. The elimination half-life is about 3-5 hours.

INDICATIONS:
EURO® (Ciprofloxacin) is indicated for the treatment of single infection or mixed infections caused by two or more susceptible organisms. It can also be used for infections caused by organisms resistant to other antibiotics including Aminoglycosides, Penicillins and Cephalosporins. As antibacterial concentrations of Ciprofloxacin are obtained in serum and body tissues as well as in the urine following administration by mouth, Ciprofloxacin has been suggested for use in the treatment of a wide range of infections caused by susceptible organisms including infections of the urinary, respiratory and gastrointestinal tracts, gonorrhoea and septicaemia. The extensive tissue penetration of Ciprofloxacin combined with its enhanced antibacterial activity (including antipseudomonal activity), enables Ciprofloxacin to be used alone (pending sensitivity results) or in combination with an Aminoglycoside or with beta-lactam antibiotics for instance when severe neutropenia is present or with an antibiotic active against anaerobes where the presence of Bacteroides fragilis is suspected.
EURO® is indicated for the treatment of the following infections caused by sensitive bacteria:
Severe systemic infections: e.g. septicaemia, bacteraemia, peritonitis, infections in immunosuppressed patients with haematological or solid tumors and in patients in intensive care unit with specific problems such as infected burns.
Respiratory tract infections: Lobar and bronchopneumonia, acute, and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyema.
Urinary tract infections: Uncomplicated and complicated urethritis, cystitis, pyelonephritis, prostatitis, epididymitis.
Skin and soft tissue infections: e.g. infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas, infected burns.
Gastro-intestinal infections: e.g. enteric fever, infective diarrhoea.
Infection of the biliary tract: e.g. cholangitis, cholecystitis, empyema of the gall bladder.
Intra-abdominal infections: e.g. peritonitis, intra-abdominal abscesses.
Bone and joint infections: e.g. osteomyelitis, septic arthritis.
Pelvic infections: e.g. salpingitis, endometritis, pelvic inflammatory diseases.
Eye, ear, nose and throat infections: e.g. otitis media, sinusitis, mastoiditis, tonsillitis.
Gonorrhoea: including urethral, rectal and pharyngeal gonorrhoea caused by beta-lactamase producing organisms or organisms moderately sensitive to penicillin.

DOSAGE AND ADMINISTRATION:
General dosage recommendations: The dosage of Ciprofloxacin is determined by the severity and type of infection, the sensitivity of the causative organism(s) and the age, weight and renal function of the patient.
Adults: The dosage range for adults is 100-750 mg twice daily.
In infections of the lower and upper urinary tract (depending on severity): 250-500 mg twice daily.
In respiratory tract infections: 250-750 mg twice daily for both upper and lower respiratory tract infections, depending on severity.
In gonorrhoea: a single dose of 250 or 500 mg.
In the majority other infections, 500-750 mg twice daily should be administered.
Impaired renal function: Dosage adjustment is not usually required except in patients with severe renal impairment (serum creatinine >265 micro mol/l or creatinine clearance <20 ml/minute). If adjustment is necessary, this may be achieved by reducing the total daily dose by half, although monitoring of drug serum levels provide the most reliable basis for dose adjustment.
Elderly: Although higher Ciprofloxacin serum levels are found in the elderly, no adjustment of dosage is necessary.
Children: The dosage should be 10-30 mg/kg/day depending upon the severity of infections, administered in two divided doses.
Duration of treatment: The duration of treatment depends upon the severity of infection, clinical response and bacteriological findings.
For acute infections the usual treatment period is 5 to 10 days with EURO® tablets. Generally treatment should be continued for 3 days after the signs and symptoms of the infection have been disappeared.

CONTRAINDICATIONS:
Ciprofloxacin is contraindicated in patients who have shown hypersensitivity to Ciprofloxacin or other quinolones.

WARNINGS AND PRECAUTIONS:
Ciprofloxacin should be used with caution in patients with a history of convulsive disorders. Crystalluria related to the use of Ciprofloxacin has been observed only rarely. Patients receiving Ciprofloxacin should be well hydrated and excessive alkalinity of the urine should be avoided.

DRUG INTERACTIONS:
Concurrent administration of Ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline related adverse reactions. If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate. Antacids containing magnesium hydroxide or aluminium hydroxide may interfere with the absorption of Ciprofloxacin resulting in serum and urine levels lower than desired, concurrent administration of these agents with Ciprofloxacin should be avoided. Probenecid interferes with renal tubular secretion of Ciprofloxacin and produces an increase in the level of Ciprofloxacin in the serum. This should be considered if patients are receiving both drugs concomitantly. As with other broad spectrum antibiotics prolonged use of Ciprofloxacin may result in overgrowth of nonsusceptible organism. Repeated evaluation of the patient's condition and microbial susceptibility testing is essential. If superinfection occurs during therapy, appropriate measures should be taken.

USE IN PREGNANCY AND LACTATION:
Reproduction studies performed in mice, rats and rabbits using parenteral and oral administration did not reveal any evidence of teratogenicity, impairment of fertility or impairment of pre/post-natal development. However as with other quinolones, Ciprofloxacin has been shown to cause arthropathy in immature animals and therefore its use during pregnancy is not recommended. Studies in rats have indicated that Ciprofloxacin is secreted in milk, administration to nursing mothers is thus not recommended.

OVERDOSAGE:
No information on overdosage is available. Routine measures such as gastric lavage should be performed as soon as possible after ingestion of Ciprofloxacin. Serum levels of Ciprofloxacin are reduced by dialysis.

SIDE EFFECTS:
Gastrointestinal disturbances e.g. nausea, diarrhoea, vomiting, dyspepsia, abdominal pain. Disturbance of the central nervous system e.g. dizziness, headache, tiredness, confusion, convulsions. Hypersensitivity reactions e.g. skin rashes, pruritus and possible systemic reactions. The following other reactions have also been reported, joint pain, mild photosensitivity and transient increase in liver enzymes (particularly in patients with previous liver damage) serum bilirubin, urea or creatinine levels.

HOW SUPPLIED:
EURO® 250 mg Tablets available in Alu Alu blister pack of 10's
EURO® 500 mg Tablets available in Alu Alu blister pack of 10's

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: ٹھنڈی اور خشک جگہ پر بچوں کی پہنچ سے دور رکھیں۔
اور سورج کی روشنی سے بچائیں۔

Marketed by:
CENRJY Pharmaceuticals

Macquin's
Manufactured by:
MACQUIN'S INTERNATIONAL
F-2/H, P.T.C. Industrial Complex,
S.I.T.E., KARACHI.
ISO 9001:2000 Certified Company