

Amiloxin

Ciprofloxacin (HCl USP)

250mg
500mg
Tablets

ایمی لوکسن
(سیپروفلاکساسین) یو ایس پی

COMPOSITION:

250mg Tablets:

Each film coated tablet contains

Ciprofloxacin HCl eq. to Ciprofloxacin USP 250mg

500mg TABLETS:

Each film coated tablet contains

Ciprofloxacin HCl eq. to Ciprofloxacin USP 500mg

PROPERTIES

Ciprofloxacin HCl (Amiloxin) is a synthetic 4-quinolone derivative with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms. These substances are also known as gyrase inhibitors.

Clinical Pharmacology

The absolute bioavailability of ciprofloxacin HCl 1 (Amiloxin) is 70-80%. The maximum blood concentration is reached just 60-90 minutes after ingestion. Half life of Ciprofloxacin HCl (Amiloxin) is about 3V2 to 4V2 hours. Protein binding is about 20% (19 to 43). 30-50% of the oral dose of Ciprofloxacin HCl (Amiloxin) is excreted as unchanged and active metabolites in the urine within 24 hours.

Ciprofloxacin HCl (Amiloxin) is present in high concentration at the sites of infections. i.e., in the body fluids and tissues. It only needs to be taken twice daily in the morning and evening.

INDICATIONS

Ciprofloxacin HCl (Amiloxin) is indicated for the treatment of the following infections caused by sensitive bacteria.

Severe systemic infections: e.g. septicaemia, bacteremia, peritonitis, infections in immunosuppressed patients with haematological or solid tumours and in patients in intensive care units with specific problems such as infected burns.

Respiratory tract infections: e.g., lobar and broncho-pneumonia acute and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyema. Ciprofloxacin HCl (Amiloxin) is not recommended as firstline therapy for the treatment of pneumococcal pneumonia. Ciprofloxacin HCl (Amiloxin) may be used for treating gram-negative pneumonia.

Ear, Nose, and Throat Infections: e.g., otitis external, otitis media, sinusitis and mastoiditis, especially if due to gram-negative bacteria (including pseudomonas spp.) Ciprofloxacin HCl (Amiloxin) is not recommended for the treatment of acute tonsillitis.

Urinary tract Infections: e.g., 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.

Eye infections: e.g., bacterial conjunctivitis. Infections 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 disease. Gonorrhoea; including urethral gonorrhoea caused by beta-lactamase producing organisms or organisms moderately sensitive to penicillin.

Ciprofloxacin HCl (Amiloxin) is also indicated for prophylaxis against infections in elective upper gastrointestinal surgery and endoscopic procedures where there is an increased risk of infection.

CONTRA-INDICATIONS: Ciprofloxacin HCl (Amiloxin) should not be used

where there is hypersensitivity to ciprofloxacin or to other hemotherapeutic agents of the quinolone group. Ciprofloxacin HCl (Amiloxin) is also contra-indicated in children and growing adolescents except where the benefits of treatment exceed the risks. Ciprofloxacin HCl (Amiloxin) should not be prescribed to pregnant and nursing women.

WARNINGS AND PRECAUTIONS:

Ciprofloxacin HCl (Amiloxin) should be used with caution in the elderly, in epileptics and patients with a history of CNS disorders and only if the benefits of treatment are considered to outweigh the risk of possible CNS side-effects. Ciprofloxacin HCl (Amiloxin) could result in an impairment of the patient's ability to drive or operate machinery particularly in conjunction with alcohol. Crystalluria related to the use of ciprofloxacin HCl (Amiloxin) (Amiloxin) has been reported. Patients receiving ciprofloxacin HCl (Amiloxin) should be well hydrated and excessive alkalinity of the urine should be avoided.

Renal disturbances e.g., transient increase in blood urea or serum creatinine, renal failure, crystalluria, nephritis, musculo-skeletal disturbances, e.g. arthralgia, myalgia, rarely tenosynovitis. Effects on haematological parameters, e.g. eosinophilia, leucopenia, thrombocytopenia, thrombocytosis, altered prothrombin levels. Special senses disturbances occur very rarely like; visual disturbances impaired taste and smell, tinnitus and transient impairment of hearing particularly at high frequencies. Tachycardia has been reported.

ADVERSE EFFECTS

Ciprofloxacin HCl (Amiloxin) is generally well tolerated. The most frequently reported adverse reactions are nausea, diarrhoea, vomiting, dyspnoea, abdominal pain, headache, restlessness, rash, dizziness and pruritus. The

following adverse reactions can rarely occur.

EFFECTS ON THE GASTRO-INTESTINAL TRACT:

Nausea, diarrhoea, vomiting, digestive disorders abdominal pain, flatulence, anorexia.

EFFECTS ON THE NERVOUS SYSTEM: Dizziness, headache, tiredness, insomnia, Diabonos, trembling, rarely, peripheral paraesthesia, sweating, unsteady gait, convulsions, anxiety states; nightmares confusion, depression, hallucinations, impaired taste and smell, visual disturbances (double vision, colour vision).

HYPERSENSITIVITY SKIN REACTIONS:

e.g. rashes, pruritus, urticaria, drug induced fever, anaphylactic / anaphylactoid reactions. Very rarely, petechiae, hemorrhagic bullae, vasculitis, Stevens Johnson syndrome & Lyell syndrome. Treatment with ciprofloxacin should be discontinued if any of the above occurs upon first administration.

EFFECTS ON CARDIOVASCULAR SYSTEM: Very rarely, tachycardia, hot flushes, migraine, fainting.

EFFECTS ON BLOOD AND BLOOD CONSTITUENTS:

Eosinophilia, leucocytopenia, anemia, leucocytosis,

VERY RARELY: Joint pain, muscular pains, mild photo-sensitivity, transient impairment in kidney function, tinnitus.

HEPATIC DISTURBANCES: e.g. transient increase in liver enzymes or serum bilirubin (particularly in patients with previous liver damage), hepatitis, jaundice and major liver disorders including hepatic necrosis.

EFFECTS ON LABORATORY VALUES / URINE DEPOSITS:

Transient rise in transaminase and alkaline phosphatase levels or cholestatic jaundice may occur. Transient increase in serum urea, creatinine and bilirubin levels, hyperglycaemia, crystalluria and haematuria.

DOSAGE & ADMINISTRATION GENERAL DOSAGE RECOMMENDATIONS:

The dosage range for adults is 250-750mg twice daily.

Acute gonorrhoea and acute uncomplicated cystitis a single dose of 250mg. Other infections of the lower and upper urinary tract (depending on severity) 250-500mg.

Upper and lower respiratory tract infections, (depending on severity) 250-750mg twice daily. Patients with lateral or actual defects in glucose-6-phosphate dehydrogenase activity or prone to hemolytic reactions should use ciprofloxacin with caution.

Elderly patients should receive a dose as low as possible taking into account the severity of the illness and the creatinine clearance.

Tablets should be swallowed whole with an adequate amount of liquid.

PRESENTATION:

Amiloxin Tablets 250mg pack of 10's. Amiloxin Tablets 500mg pack of 10's.

PRECAUTION:

- Use as prescribed by the physician.
- Keep out of the reach of children.
- Store at room temperature.
- Protect from direct sunlight, heat & moisture



Manufactured by

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