إنسيبرو
ميفوفاكين

لا يوجد نص يمكن قراءته بشكل طبيعي من الصورة المقدمة.
Emicprro® ciprofloxacin

Composition:
Emicprro® ciprofloxacin 100mg/5ml (16.7mg/ml) for injection.

Properties:
Emicprro® ciprofloxacin is a quinolone derivative, broad-spectrum antimicrobial agent with activity against a wide range of gram-positive and gram-negative organisms. It is particularly active against many aerobic and anaerobic gram-negative bacteria, as well as some aerobic and anaerobic gram-positive bacteria. Emicprro® ciprofloxacin has moderate activity against gram-positive bacteria such as staphylococci (except MRSA and sulfonamide-resistant strains) and streptococci. The bactericidal action of Emicprro® ciprofloxacin results in the interruption of the enzyme DNA gyrase that is needed for the synthesis of bacterial DNA.

Indications:
Emicprro® ciprofloxacin is indicated for the treatment of the following infections caused by sensitive bacteria:

In Adults:
- Respiratory tract infections: e.g., lobar and bronchopneumonia, acute and chronic bronchitis, acute exacerbation of chronic bronchitis, bronchiectasis, empyema (caused by at least one susceptible organism), pneumonia not requiring hospitalization (caused by at least one susceptible organism) (if ciprofloxacin is used as first-line therapy).
- Urinary tract infections (UTIs): e.g., acute uncomplicated and complicated urinary infections, cystitis, pyelonephritis, prostatitis.
- Skin and soft tissue infections: e.g., infected ulcers, wounds, infections of abdominal, genital and perineal areas.
- Bone and joint infections: e.g., osteomyelitis, septic arthritis.
- Ophthalmological infections: e.g., conjunctivitis, keratitis, endophthalmitis of the eye.
- Gastro-intestinal infections: e.g., enteritis, diarrhea, typhoid fever.
- Pelvic infections: e.g., salpingitis, endometritis, and pelvic inflammatory disease.
- Severe systemic infections: e.g., sepsis, septic arthritis, peritonitis, and infections in immunocompromised patients.
- Gonococcal infections: including urinary, rectal and pharyngeal infections caused by beta-lactamase producing organisms or organisms moderately sensitive to penicillins.
- Empyema (caused by at least one susceptible organism) (if ciprofloxacin is used as first-line therapy).
- Intra-abdominal infections (e.g., peritonitis, intra-abdominal abscesses).
- Respiratory tract infections (caused by at least one susceptible organism) (if ciprofloxacin is used as first-line therapy).

In Children:
- For the treatment of acute pulmonary exacerbation of cystic fibrosis associated with P. aeruginosa in patients aged 6 years and above.
- Inhalation Aerosol in Adults and Children: To reduce the incidence or progression of disease following confirmed or suspected infection caused by Pseudomonas aeruginosa.

Dosage and Administration:
The dosage regimen of Emicprro® ciprofloxacin is determined by the severity and type of infection, the susceptibility of the causative organisms and the age, weight and renal function of the patient. Ciprofloxacin is well tolerated in adults with an adequate amount of liquid intake.

If Emicprro® Tablets are taken on an empty stomach, the active substance is absorbed more rapidly than in the fed state. Therefore, in the context of daily dose recommendations, it is important to take Emicprro® Tablets a few minutes before or at least 2 hours after meals (e.g. milk, yoghurt, calcium fortified orange juice). However, a normal diet will not change the overall amount absorbed and thus not significantly affect ciprofloxacin absorption.

The average dose for adults is 250-750mg twice daily. The following dosages for specific types of infections are recommended:

Recommended Adult Dose

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose (mg) ciprofloxacin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>250-500 mg t.i.d.</td>
</tr>
<tr>
<td>Upper and lower urinary tract infections</td>
<td>250-750 mg t.i.d.</td>
</tr>
<tr>
<td>Prophylaxis</td>
<td></td>
</tr>
<tr>
<td>Cystic fibrosis patients with pseudomonal LRTI</td>
<td>750 mg q.d.</td>
</tr>
<tr>
<td>Other infections as stated above</td>
<td>750 mg q.d.</td>
</tr>
<tr>
<td>Inhalation Aerosol</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>750 mg q.d.</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>80-90 mg/kg q.d. for the first 24 hours, then 80-120 mg/kg q.d. for the next 48 hours in patients with severe obstructive pulmonary disease</td>
</tr>
</tbody>
</table>

**Precautions:**
- Ciprofloxacin should be used with caution in epilepsy and patients with a history of CNS disorders and only if the benefit of treatment is considered worth the risk. CNS side-effects have been reported after first administration of ciprofloxacin in some patients. Treatment should be discontinued if the side-effects are severe or intolerable.
- Ciprofloxacin is contraindicated in patients with severe hepatic or renal dysfunction or who are on concurrent treatment with high-dose aminoglycosides. Patients with a history of or actual deficits in glucose-6-phosphate dehydrogenase activity are prone to haemolytic reactions with ciprofloxacin, although these reactions have not been reported in patients treated with ciprofloxacin. Treatment should be discontinued if a haemolytic reaction occurs.
- Patients with a family history of or actual deficits in glucose-6-phosphate dehydrogenase activity are prone to haemolytic reactions with ciprofloxacin, although these reactions have not been reported in patients treated with ciprofloxacin. Treatment should be discontinued if a haemolytic reaction occurs.
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**Side Effects:**
Ciprofloxacin is generally well tolerated. The most frequently reported adverse reactions are nausea, vomiting, and headache. The following adverse reactions have been observed:

- Hypersensitivity reactions: e.g., rash, pruritus, urticaria, phototoxicity, drug-induced fever, anaphylactic shock (anaphylactoid reactions including angioedema and dyspnoea). Rarely, erythema nodosum, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and aplastic anaemia have been reported.
- Nervous system: cerebral haemorrhage, cerebral ischaemia, cerebrovascular accident, deep vein thrombosis, stroke, transient ischaemic attack, convulsions, and peripheral neuropathy.
- Gastro-intestinal: rarely, hepatitis, cholestatic jaundice, eosinophilic enteritis, enterocolitis, pseudomembranous enterocolitis, abscess of the liver, pancreatitis. There are isolated reports of acute hepatitis.
- **Gastro-intestinal:** e.g., nausea, vomiting, diarrhea, abdominal pain, anorexia, abdominal distension, dyspepsia, and dyspepsia.
- **Musculoskeletal:** e.g., myalgia, arthralgia, myositis, periarthritis.
- **Respiratory:** e.g., bronchitis, cough, pharyngitis, laryngitis, sinusitis, and pharyngitis.
- **Skin:** e.g., urticaria, hives, angioedema, urticaria, erythema, pruritus, rash, and bullous rash.
- **Ocular:** e.g., conjunctivitis, keratitis, iritis, and retinitis.
- **Genitourinary:** e.g., decreased libido, testicular pain, and renal failure.
- **CNS:** e.g., headache, dizziness, depression, drowsiness, tremor, convulsions, confusion, hallucinations, somnolence, altered mental status, insomnia, anxiety, hypomania, hyperactivity, depression.
- **Hepatic:** e.g., jaundice, cholestasis, hepatitis, and liver failure. Although, ciprofloxacin-induced hepatitis has been reported, which may progress to self-limited hepatic failure.

**Effects on ability to drive and use machines:**
Ciprofloxacin could result in impairment of the patient’s ability to drive or operate machinery, particularly in conjunction with alcohol.

**Use in Pregnancy and Lactation:**
Reproduction studies performed in mice, rats and rabbits using perinatal and/or adult administration did not reveal any evidence of teratogenicity, impairment of fertility or impairment of pregnancy outcome. However, as with all quinolones, ciprofloxacin has been shown to cause arthrotrophic changes in immature animals, and therefore, ciprofloxacin should be avoided in pregnant women.