Martin Dow

Mercip Infusion 200 mg (Ciprofloxacin) Injection USP

مرسیپ انفیوژن ۲۰۰ ملی گرام

Broad-Spectrum Antibiotic

1. **COMPOSITION**

Each 100 ml contains:
Ciprofloxacin Lactate, MS equivalent to Ciprofloxacin (USP) ..... 200mg.
Sodium Chloride content is 900 mg.

2. **DESCRIPTION**

Ciprofloxacin is a synthetic broad-spectrum antimicrobial agent for intravenous (I.V.) administration. Ciprofloxacin is a faint to light yellow crystalline powder. It is soluble in dilute (0.1N) hydrochloric acid and is practically insoluble in water and 16 ethanol.

3. **THERAPEUTIC INDICATIONS**

Adults

- Lower respiratory tract infections due to Gram-negative bacteria: Exacerbations of chronic obstructive pulmonary disease, Broncho-pulmonary infections in cystic fibrosis or in bronchiectasis, Pneumonia.
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria.
- Urinary tract infections.
- Epididymo-orchitis including cases due to Neisseria gonorrhoeae.
- Pelvic inflammatory disease including cases due to Neisseria gonorrhoeae.
- Infections of the gastro-intestinal tract (e.g. travelers' diarrhoea).
- Intra-abdominal infections.
- Infections of the skin and soft tissue caused by Gram-negative bacteria.
- Malignant external otitis.
- Infections of the bones and joints.
- Treatment of infections in neutropenic patients.
- Prophylaxis of infections in neutropenic patients.
- Inhalation anthrax (post-exposure prophylaxis and curative treatment).

Children and adolescents

- Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas Aeruginosa.
- Complicated urinary tract infections and pyelonephritis.
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)
- Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered to be necessary.

4. **DOSAGE AND ADMINISTRATION**

• Geriatric: Should receive a dose selected according to the severity of the infection and the patient`s creatinine clearance.
• Hepatic impairment: No dose adjustment required.

ADULT DOSAGE GUIDELINES

INDICATION	DAILY DOSE (IV Inf.)	DURATION OF THE TREATMENT
Infections of the lower respiratory tract & upper respiratory tract		
	400 mg thrice daily to 400 mg three times a day	7 to 14 days
	400 mg thrice daily to 400 mg three times a day	28 days up to 3 months
Urinary Tract Infections		
	400 mg thrice daily to 400 mg three times a day	7 to 21 days, it can be continued for longer than 21 days in some specific circumstances (such as abscesses)
	400 mg thrice daily to 400 mg three times a day	2 to 4 weeks (acute)
Genital Tract Infections		
	400 mg thrice daily to 400 mg three times a day	at least 14 days
Infections of the gastro-intestinal tract and intra-abdominal infections		
	400 mg thrice daily	1 day
	400 mg thrice daily	2 day
	400 mg thrice daily	3 days
	400 mg thrice daily	7 days
	400 mg thrice daily to 400 mg three times a day	5 to 14 days
Infections of the skin and soft tissue	400 mg thrice daily to 400 mg three times a day	7 to 14 days
Bone and joint infections	400 mg thrice daily to 400 mg three times a day	max. of 3 months
Neutropenic patients with fever that is suspected to be due to a bacterial infection.*	400 mg thrice daily to 400 mg three times a day	Therapy should be continued until the infection has resolved
Inhalation anthrax (post-exposure prophylaxis and curative treatment for persons requiring parenteral treatment.**	400 mg thrice daily	60 days from the confirmation of Bacillus anthracis exposure.

*Ciprofloxacin should be co-administered with appropriate antibacterial agent(s) as recommended by official guidance.
**Drug administration should begin as soon as possible after suspected or confirmed exposure.

RECOMMENDED STARTING AND MAINTENANCE DOSES FOR PATIENTS WITH IMPAIRED RENAL FUNCTION

Creatinine Clearance [mL/min/1.73 m²]	Serum Creatinine [µmol/L]	Dose [mg]
> 60	< 124	See Usual Dosage
30-60	124 to 168	200-400 mg every 12 h
< 30	> 169	200-400 mg every 24 h
Patients on haemodialysis	> 169	200-400 mg every 24 h (after dialysis)
Patients on peritoneal dialysis	> 169	200-400 mg every 24 h

PEDIATRIC DOSAGE GUIDELINES

Infection	Dose (mg/kg)	Total Duration
Complicated Urinary Tract and acute Pyelonephritis (Patients from 1 to 17 years of age)	6 to 10 mg/kg three times a day, maximum 400 mg per dose	10 – 21 days*
Cystic fibrosis	10 mg/kg three times a day, maximum 400 mg per dose	10 to 14 days
Inhalation Anthrax (post exposure)** post-exposure curative treatment for persons requiring parenteral treatment	10 mg/kg – 15 mg/kg body weight twice daily, maximum 400 mg per dose	60 days* from the confirmation of *Bacillus anthracis* exposure
Other severe infections	10 mg/kg three times a day maximum of 400 mg per dose	According to the type of infections

Adults infusion duration is 30mins and for children it is 60 mins.

5. **CONTRAINDICATIONS**

Hypersensitivity to the active substance, to other quinolones or to any of the excipients.

6. **SPECIAL WARNINGS AND PRECAUTIONS**

- **Tendinitis and tendon rupture** (especially Achilles tendon), sometimes bilateral, may occur with ciprofloxacin, as soon as the first 48 hours of treatment. Avoid use with history of tendon disorder in patients.
- **Severe infections and mixed infections with Gram-positive and anaerobic pathogens, Infections of the bones and joints:** Monotherapy not recommended.
- Not recommended for the treatment of streptococcal infections due to inadequate efficacy.
- Genital tract infections when known to be due to Neisseria gonorrhoeae it is important to obtain local information on the prevalence of resistance to ciprofloxacin and susceptibility based on laboratory testing.
- **Travellers' diarrhoea:** Resistance to ciprofloxacin should be taken into account.
- If vision becomes impaired, an eye specialist should be consulted immediately.
- Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.
- **Complicated urinary tract infections and pyelonephritis:** Consider ciprofloxacin when other treatment have failed.
- Ciprofloxacin should be used with caution in patients with myasthenia gravis.
- Ciprofloxacin has been shown to cause photosensitivity reactions.
- Ciprofloxacin like other quinolones are known to trigger seizures or lower the seizure threshold. Consider discontinuation if seizure occur.
- Use caution in patients with known risk factors for prolongation of the QT interval.
- The occurrence of severe and persistent diarrhoea during or after treatment may indicate an antibiotic-associated colitis requiring immediate treatment.
- Crystalluria has been reported. Patients receiving ciprofloxacin should be well hydrated and excessive alkalinity of the urine should be avoided.
- Cases of hepatic necrosis and life-threatening hepatic failure have been reported.
- Haemolytic reactions have been reported with G6PD deficiency.

7. **DRUG INTERACTIONS**

- **Drugs known to prolong QT interval:** Use with caution.
- **Probenecid** interferes with renal secretion of ciprofloxacin and increases ciprofloxacin serum concentrations.
- **Tizanidine:** Increased serum tizanidine concentration is associated with a potentiated hypotensive and sedative effect. Avoid coadministration.
- **Methotrexate:** Avoid concomitant use due to inhibition of renal tubular transport of methotrexate.
- **Theophylline, Phenytoin, Cyclosporin, Clozapine, Sildenafil and Other xanthine derivatives:** Concurrent administration can cause an undesirable alteration in serum concentration of these. Monitoring required.
- **Vitamin K antagonists:** Simultaneous administration of ciprofloxacin with a vitamin K antagonist may augment its anti-coagulant effects. Monitor INR.
- **Glibenclamide:** Coadministration intensifies hypoglycemia.
- **Ropinirole, Duloxetine:** Monitoring required as coadministration with these can result in increase in Cmax and AUC.
- **Lidocaine, Agomelatine:** Possible interaction may occur as they are CYP450 1A2 isoenzyme inhibitors.
- **Zolpidem:** Co-administration may increase blood levels of zolpidem, avoid use.

8. **SPECIFIC POPULATION**

- **Pregnancy:** No malformation or toxicity reported. However, as a precaution, avoid use.
- **Nursing:** It is excreted in breast milk. Due to the potential risk of articular damage. Avoid use.
- **Effects on ability to drive and use machines:** Due to its neurological effects, ciprofloxacin may affect reaction time. Avoid use of machines.

9. **ADVERSE EFFECTS**

- **Common** Vomiting, transient increase in transaminases, rash.
- **Uncommon** Thrombocytopenia, thrombocythemia, confusion and disorientation, hallucinations, par- and dysaesthesia, seizures, vertigo, visual disturbances, hearing loss, tachycardia, vasodilatation, hypotension, transient hepatic impairment, cholestatic icterus, renal failure, edema.
- **Rare** Pancytopenia, bone marrow depression, anaphylactic shock, psychotic reactions, migraine, olfactory nerve disorders, hearing impaired, vasculitis, pancreatitis, liver necrosis, petechiae, tendon rupture.

10. **CLINICAL PHARMACOLOGY**

Mechanism of action: As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from the inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination.

11. **OVERDOSE**

An overdose of 12 g has been reported to lead to mild symptoms of toxicity. An acute overdose of 16 g has been reported to cause acute renal failure. Symptoms in overdose consist of dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria and hematuria. Reversible renal toxicity has been reported. In the event of overdose, symptomatic treatment should be implemented.

عمومی خوراک:

بڑوں کے لئے: ۱۰۰ تا ۲۰۰ ملی گرام دن میں دو مرتبہ یا ڈاکٹر کی ہدایت کے مطابق۔

بزرگوں کے لئے: عمومی طور پر کم خوراک ان کی بیماری کی شدت اور کریٹنن کلیرنس کو مدنظر رکھ کے دی جائے۔

Presentation:
Mercip Infusion
1 vial of 100 ml Infusion solution containing Ciprofloxacin Lactate, MS equivalent to Ciprofloxacin (USP) ..... 200 mg.
Sodium chloride content is 900 mg.

Storage:
Store below 30 °C.
Protect from light and heat.
Keep all medicines out of the reach of children.

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور گرمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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