

BAQUINOR®

Ciprofloxacin

Infus

Tiap 100 ml mengandung:
Siprofloksasin Laktat Monohidrat yang setara dengan
Siprofloksasin 200 mg
Air untuk injeksi ad 100 ml

FARMAKOLOGI

Siprofloksasin merupakan antibiotik golongan fluorokui-nolon, bekerja dengan cara mempengaruhi enzim DNA gyrase pada bakteri.

Siprofloksasin merupakan antibiotik untuk bakteri gram-positif dan gram-negatif yang sensitif.

Bakteri gram-positif yang sensitif: *Enterococcus faecalis*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*.

Bakteri gram-negatif yang sensitif: *Campylobacter jejuni*, *Citrobacter diversus*, *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia rettgeri*, *Providencia stuartii*, *Pseudomonas aeruginosa*, *Salmonella typhi*, *Serratia marcescens*, *Shigella flexneri*, *Shigella sonnei*.

INDIKASI

Untuk pengobatan infeksi berat pasien rawat inap rumah sakit yang tidak bisa diberi Siprofloksasin oral atau pemberian oral tidak tepat.

Infeksi yang disebabkan oleh bakteri yang sensitif terhadap Siprofloksasin pada:

- Infeksi saluran kemih termasuk prostatitis.
- Uretritis dan servisitis gonore.
- Infeksi saluran cerna, demam tifoid yang disebabkan oleh *Salmonella typhi*.
Khasiat Siprofloksasin untuk eradikasi *chronic typhoid carrier* belum diketahui.
- Infeksi saluran napas, kecuali pneumonia akibat *Streptococcus*.
- Infeksi kulit dan jaringan lunak.
- Infeksi tulang dan sendi.

KONTRA-INDIKASI

- Penderita yang hipersensitif terhadap Siprofloksasin atau antibiotik derivat kuinolon lainnya.
- Wanita hamil dan ibu menyusui.
- Anak-anak dibawah usia 18 tahun.

EFEK SAMPING

- Efek terhadap saluran cerna
Mual, diare, muntah, gangguan pencernaan, dispepsia, nyeri abdomen, flatulensi, anoreksia, disfagia.
Kalau terjadi diare berat atau persisten selama atau sesudah pengobatan, segera konsultasi pada dokter karena gejala tersebut mungkin menutupi kelainan yang lebih serius (kolitis pseudomembran) yang memerlukan tindakan segera. Bila hal ini terjadi, pemberian Siprofloksasin harus segera dihentikan dan diganti dengan obat lain yang lebih sesuai (misalnya vankomisin per oral 4 x 250 mg sehari). Obat-obat yang menghambat peristaltik merupakan kontra-indikasi.
- Efek terhadap sistem saraf
Pusing, sakit kepala, rasa letih, insomnia, agitasi, tremor. Sangat jarang: paralgesia perifer, berkeringat, kejang, ansietas, mimpi buruk, kebingungan, depresi, halusinasi, gangguan pengecap dan penciuman, gangguan penglihatan (misal penglihatan ganda, penglihatan warna). Reaksi kadang-kadang timbul setelah pemberian Siprofloksasin untuk pertama kalinya. Dalam hal ini Siprofloksasin harus segera dihentikan dan segera konsultasi pada dokter.
- Reaksi hipersensitivitas
Reaksi kulit seperti kemerahan pada kulit, pruritus, *drug fever*. Reaksi anafilaktik/anafilaktoid (seperti edema pada wajah, vaskuler dan laring, dispnea yang bertambah berat sehingga terjadi syok yang mengancam jiwa). Dalam hal ini Siprofloksasin segera distop, tindakan keadaruratan medis (misal mengatasi syok) harus segera dilakukan.
Sangat jarang: *punctate skin hemorrhages (petechiae)*, pembentukan blister disertai pendarahan kulit (*haemorrhagic bullae*) dan nodulus-nodulus kecil (papula) disertai pembentukan krusta yang menunjukkan adanya kelainan vaskuler (vaskulitis), sindrom Stevens-Johnson.
- Efek terhadap renal/urogenital
Nefritis interstisial, gagal ginjal, termasuk gagal ginjal sementara, poliuria, retensi urine, pendarahan uretra, vaginitis dan asidosis.
- Efek terhadap hati
Hepatitis.
Sangat jarang: kelainan hati yang luas seperti nekrosis hati.
- Efek terhadap sistem kardiovaskuler
Jarang: takikardia, palpitasi, *atrial flutter*, ventrikuler ek-topi, sinkop, hipertensi, angina pectoris, miokardial infark, *cardiopulmonary arrest*, trombosis otak, wajah merah dan panas, migren, pingsan.

- Lain-lain

Jarang: nyeri sendi, lemas seluruh tubuh, nyeri otot, tendovaginitis, fotosensitivitas ringan, tinitus, gangguan pendengaran terutama untuk frekuensi tinggi, epistaksis, edema pulmonal atau laringalgia, hemoptisis, dispnea, bronkospasme, emboli pulmonal.

- Efek pada darah

Eosinofilia, leukositopenia, leukositosis, anemia, granulositopenia.

Sangat jarang: trombositopenia, trombositosis, kelainan protrombin.

- Efek pada nilai laboratorium/deposit urine

Kadar transaminase dan alkali fosfatase dalam darah mungkin meningkat untuk sementara; ikterus kolestatik dapat terjadi terutama pada pasien yang pernah mengalami kelainan; peningkatan kadar urea, kreatinin dan bilirubin darah untuk sementara; hiperglikemia; pada kasus tertentu: kristaluria dan hematuria.

PERHATIAN

- Hati-hati pemberian pada penderita dengan gangguan fungsi ginjal (lihat dosis).
- Pemberian tidak boleh melebihi dosis yang dianjurkan.
- Siprofloksasin harus diberikan dengan hati-hati pada penderita usia lanjut.
- Pada kasus epilepsi dan pasien yang pernah mengalami gangguan susunan saraf pusat (misalnya ambang kejang rendah, riwayat konvulsi, aliran darah ke otak berkurang dan *stroke*), Siprofloksasin hanya diberikan jika manfaatnya lebih besar dibanding risikonya, karena pasien demikian mungkin akan menderita efek samping susunan saraf pusat.
- Meskipun diberi sesuai dengan resep dokter, obat ini dapat mengganggu respons pasien, kemampuan mengemudi dan menjalankan mesin. Gangguan ini akan lebih berat jika diberi bersama alkohol.
- Hindarkan penderita dari sinar matahari yang berlebihan. Bila terjadi fototoksitas pengobatan harus segera dihentikan.

INTERAKSI OBAT

- Pemberian Siprofloksasin bersama teofilin dapat meningkatkan kadar teofilin dalam plasma sehingga dapat menimbulkan efek samping teofilin. Apabila kombinasi ini tidak dapat dihindarkan, kadar teofilin dalam plasma harus dimonitor dan dosis teofilin harus dikurangi. Jika kadar teofilin tidak dapat dimonitor, pemberian Siprofloksasin harus dihindari.
- Kenaikan kadar kreatinin serum untuk sementara terlihat pada pemberian Siprofloksasin bersama Siklosporin. Dalam hal ini, kadar kreatinin serum harus sering dipantau (dua kali seminggu).
- Harus dipertimbangkan kemungkinan terjadinya interaksi pada pemberian Siprofloksasin bersama probenesisid.
- Pemberian bersama Siprofloksasin dan antikoagulan oral dapat memperpanjang waktu pendarahan.
- Pemberian bersama metoklopramid dapat mempercepat absorpsi Siprofloksasin.

DOSIS

Dewasa:

- Infeksi ginjal yang tidak terkomplikasi dan infeksi saluran kemih bagian atas dan bawah: 2 x 100 mg sehari.
- Infeksi lain: 2 x 200 mg sehari.
- Gonore akut dan sistitis akut yang tidak terkomplikasi pada wanita: infus tunggal 100 mg. Setelah pemberian intravena pengobatan dapat diteruskan secara oral. Penderita usia lanjut mungkin diberikan dosis lebih rendah tergantung dari beratnya penyakit dan bersihan kreatinin.

Dosis pada penderita dengan gangguan fungsi ginjal: Bila bersihan kreatinin < 20 ml/menit, maka dosis normal hanya diberikan 1 kali sehari atau jika diberikan 2 kali sehari maka dosis harus dikurangi separuhnya.

HARUS DENGAN RESEP DOKTER

Overdosis

Jika terjadi overdosis akut, penderita harus terus diobservasi dan diberi terapi penunjang. Penderita harus diberi cairan elektrolit yang cukup. Siprofloksasin hanya dikeluarkan <10% setelah hemodialisis dan peritoneal dialisis.

KEMASAN

Botol gelas infus dengan isi bersih 100 ml.
No. Reg.: DKL982226349A1
Softbag infus dengan isi bersih 100 ml.
No. Reg.: DKL982226349A2

PENYIMPANAN

Simpan pada suhu di bawah 25°C, terlindung dari cahaya.

Dibuat oleh: **PT SANBE FARMA**
Bandung - Indonesia

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BAQUINOR®

Ciprofloxacin

Infusion

Each 100 ml contains:
Ciprofloxacin Lactate Monohydrate equivalent to
Ciprofloxacin 200 mg
Water for injection ad 100 ml

PHARMACOLOGY

Ciprofloxacin is a fluoroquinolone antibiotic which acts through interference with bacterial DNA gyrase enzyme. Ciprofloxacin is an antibiotic active against gram-positive and gram-negative bacteria.

Sensitive gram-positive bacteria: *Enterococcus faecalis*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*.

Sensitive gram-negative bacteria: *Campylobacter jejuni*, *Citrobacter diversus*, *Citrobacter freundii*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia rettgeri*, *Providencia stuartii*, *Pseudomonas aeruginosa*, *Salmonella typhi*, *Serratia marcescens*, *Shigella flexneri*, *Shigella sonnei*.

INDICATIONS

For the treatment of severe infection in hospitalized patients who cannot receive oral Ciprofloxacin or oral route of administration is not suitable.

Infections caused by susceptible bacteria to Ciprofloxacin such as:

- Urinary tract infections including prostatitis.
- Urethritis and cervicitis gonorrhoea.
- Gastrointestinal tract infections, typhoid fever caused by *Salmonella typhi*.
Efficacy in the eradication of the chronic typhoid carrier state has not been demonstrated.
- Respiratory tract infections, except pneumonia caused by *Streptococcus*.
- Skin and soft tissue infections.
- Bone and joint infections.

CONTRA-INDICATIONS

- Patients who have shown hypersensitivity to Ciprofloxacin or other quinolone derivative antibiotics.
- Pregnant women and nursing mothers.
- Adolescents less than 18 years of age.

ADVERSE REACTIONS

- Effects on the gastrointestinal tract
Nausea, diarrhoea, vomiting, gastrointestinal disturbance, dyspepsia, abdominal pain, flatulence, anorexia, dysphagia.

In the event of severe or persistent diarrhoea during or after treatment, a doctor should be consulted since this symptom may hide a serious intestinal disease (pseudomembranous colitis), requiring immediate treatment. In such cases, Ciprofloxacin must be discontinued and appropriate therapy initiated (e.g. vancomycin, orally, 4 x 250 mg/daily). Drugs that inhibit peristalsis are contraindicated.

- Effects on the nervous system
Dizziness, headache, tiredness, insomnia, agitation, tremor.

Very rarely: peripheral paralgesia, sweating, convulsions, anxiety, nightmares, confusion, depression, hallucinations, impaired taste and smell, visual disturbances (e.g. double vision, colour vision). In some instances, these reactions occurred after the 1st administration of Ciprofloxacin already. In these cases, Ciprofloxacin has to be discontinued and the doctor should be informed immediately.

- Hypersensitivity reactions
Skin reactions, e.g. rashes, pruritus, drug fever. Anaphylactic/anaphylactoid reactions (e.g. facial, vascular and laryngeal oedema, dyspnea progressing to life-threatening shock). In these cases, Ciprofloxacin has to be discontinued, medical treatment (e.g. treatment for shock) is required.

Very rarely: punctate skin haemorrhages (petechiae), blister formation with accompanying skin haemorrhages (haemorrhagic bullae) and small nodules (papules) with crust formation showing vascular involvement (vasculitis), Stevens-Johnson syndrome.

- Effects on the renal/urogenital
Interstitial nephritis, renal failure, including transient renal failure, polyuria, urinary retention, urethral bleeding, vaginitis and acidosis.

- Effect on the liver
Hepatitis.
Very rarely: major liver disorders including hepatic necrosis.

- Effects on the cardiovascular system
Rarely: tachycardia, palpitation, atrial flutter, ventricular ectopy, syncope, hypertension, angina pectoris, myocardial infarction, cardiopulmonary arrest, cerebral thrombosis, hot flushes, migraine, faint.

- Other side effects
Rarely: joint pains, general feeling of weakness, muscular pains, tendovaginitis, mild photosensitivity, tinnitus, transitory impairment of hearing especially at high frequencies, epistaxis, laryngalgia or pulmonary edema, hemoptysis, dyspnea, bronchospasm, pulmonary embolism.

- Effects on the blood
Eosinophilia, leukocytopenia, leukocytosis, anaemia, granulocytopenia.

Very rarely: thrombocytopenia, thrombocytosis, prothrombin abnormality.

- Influence on laboratory parameters/urinary sediment
There can be a temporary increase in the transaminases and alkaline phosphatase; cholestatic icterus might occur particularly in patients who have had abnormalities; temporary increase in urea, creatinine and bilirubin in the serum; hyperglycaemia; in individual cases: crystalluria and haematuria.

PRECAUTIONS

- It should be used with caution in patients with impaired renal function (see dosages).

- Do not exceed the recommended dose.

- Ciprofloxacin should be used with caution in elderly patients.

- In epileptics and in patients who have suffered from previous CNS disorders (e.g. lowered convulsion threshold, previous history of convulsion, reduced cerebral blood flow and stroke), Ciprofloxacin should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible central nervous side effects.

- Even when the drug is taken exactly as prescribed, it can affect the speed of reaction resulting in the impaired ability to drive or to operate machinery. This applies particularly in combination with alcohol.

- Excessive sunlight should be avoided. If phototoxicity occurs, discontinue use of this drug.

DRUG INTERACTIONS

- Concurrent administration of Ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline. This may result in increased risk of theophylline-related reactions. If concomitant use cannot be avoided, serum levels of theophylline should be monitored and dosage adjustments be made as appropriate. Where monitoring of plasma levels is not possible, the use of Ciprofloxacin should be avoided.

- A transient rise in the concentration of serum creatinine was observed when Ciprofloxacin and cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).

- The possibility of interaction between Ciprofloxacin and probenecid should be taken into consideration.

- Prolongation of bleeding time has been reported during concomitant administration of Ciprofloxacin and oral anticoagulants.

- The use of metoclopramide with Ciprofloxacin may accelerate the absorption of Ciprofloxacin.

DOSAGES

Adults:

- Uncomplicated renal infections and infections of the lower and upper urinary tract: 100 mg twice daily.

- Other infections: 200 mg twice daily.

- Acute gonorrhoea and acute uncomplicated cystitis in women: a single dose of 100 mg. Treatment by intravenous administration may be followed by oral administration.

Elderly patients should receive a dose as low as possible, this will depend on the severity of the illness and on the creatinine clearance.

Dosage in patients with impaired renal function:

Where creatinine clearance is < 20 ml/min, the usual dose should be given once daily or when given twice daily the dose should be reduced by half.

ON MEDICAL PRESCRIPTION ONLY

Overdosage

In the event of acute overdosage, the patient should be carefully observed and given supportive treatment. Adequate hydration must be maintained. Only <10% of Ciprofloxacin is removed from the body after hemodialysis or peritoneal dialysis.

PRESENTATIONS

Glass bottle infusion with net contents of 100 ml.

Reg. No.: DKL9822226349A1

Softbag infusion with net contents of 100 ml.

Reg. No.: DKL9822226349A2

STORAGE

Store at temperature below 25°C, away from light.

Manufactured by: **PT SANBE FARMA**
Bandung - Indonesia

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