

CIPROLON® Infusion

Ciprofoxacin, the active ingredient of Ciprolon, belongs to the quinolone group of substances. The main site of action of quinolones is a bacterial enzyme (gyrase) which plays a vital role in bacterial metabolism and reproduction. Blocking this enzyme with ciprofloxacin (a gyrase inhibitor) has a bacterioidal effect on the disease pathogens (i.e. it kills the germs). MINICATIONS

Adults
For the treatment of infections caused by organisms susceptible to ciprofloxacin:

- For the restrient or intections caused by significant control functions:

 Indications:

 of the resignation, and the many problem germs' (e.g., Klebsiella, Enterobacter, Proteus, Pseudomo Lagionella, Staphylococcus, Escherichia col) react very sensitively to Ciprolon. Most cases of pneumonia which do not requi hospital freatment are caused by Streptococcus pneumoniae. In such cases Ciprolon is not the drug of first divolon. of the middle and the paranasal airuses (circuistis), particularly when they are caused by problem germs sur Pseudomonas or Staphylococcus. A different artibiotic should be used for acute tonsilitis.

- of the middle ser (offits media) and the paramasal ansues (circuits), particularly when they are caused by problem germs such as Pseudomona or Staphydococus. A different antibiotic should be used for scute tonalitis.
- of the yes.
- of the kidneys and/or efferent urinary tract
- of the kidneys (circuits)
- of the kidneys (circuits)
- of the sidneys (circuits)
- of the sidneys (circuits)
- of the abdominal cavely, e.g., the gastrointestinal tract, the biliary tract and pertinerum (pertionits)
- of the sidn and soft fissues
- of the sidn and soft fissues
- illicot policering (sepsia)
- For children and adolescents aged between 5 and 17.
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- For children and odelescents aged control in the traction of the sidney of glandials ascertosis in the bronch and digester tract) caused by P averginosa, provided that more effective paremal treatment options do not appear practicable. Ciprolos is not recommended for other indicators.
- for immediate therapy and for treatment of antivax following hishalston of a tracks. The efficacy, of Ciprolos in

For immediate therapy and for treatment of anthrax following inhalation of anthrax (Bacillus anthracis). The efficacy: of Ciprolon in For immediate therapy and for treatmers of anthrax has been confirmed in studies.

 DOSAGE AND ADMINISTRATION

Unless otherwise prescribed, the following discountry.

Indications	Single dose/ Frequency
	Quantity of active ingredient (mg ciprofloxacin)
Respiratory tract infections (depending on the severity and pathogen)	200-400 q 12 hrs
Complicated infections of the urinary tract	200 q 12 hrs
Diarrhoea	200 q 12 hrs
Other infections	200-400 q 12 hrs
Patients with particularly severe, life-threatening infections, especially those involving Pseudomonas, Staphylococcus or Streptococcus, e.g. pneumonia caused by Streptococcus	400 q 8 hrs
Recurrent infection episodes in mucoviscidosis patients (an inherited metabolic disorder with increased production and increased viscosity of glandular secretions in the bronchi and digestive track.	400 q 8 hrs
Infections of bones and joints	400 q 8 hrs
Blood poisoning (sepsis)	400 q 8 hrs
Infections of the peritoneum (peritonitis)	400 q 8 hrs
Anthrax	400 q 12 hrs

The maximum single dose for children must not exceed 400 mg.

Treatment should commence immediately after the suspected or confirmed inhalation of anthrax pathoglens.

Note: In addition to Opproto, other finizon solutions containing lower and higher doses of the active ingredient are available for oral thirapy.

In this removes therapy, and other delivery forms are available for oral thirapy.

Extra removes the substitution can be followed by further treatment on an oral basis.

Elderly salations should receive as lowe dose.

clearance).

Children and adolescents
The recommended dose for acute infection episodes caused by P. aeruginosa in mucoviscidosis patients (an inherited metabolic disorder with increased production and increased viscosity of glandular secretions in the bronch and digestive tract) is 3 x daily 10 mg/kg i.v. (maximum 1,200 mg/day).

Patients with impaired renal and heoatic function:

Autre

10 mg/sg 1x (maximum' 1,200 mg/day).
Pallentins with impaired renal and heads function:

Adulta

Adult

No information is available on the influence of impaired ornal and hepatic function on the dosage for children and adolescents.

WARNINGS
The influent time is 30 minutes for 1 bottle containing 100 ml influents solution equivalent to 200 mg ciprofloxacion.

The influence of the containing 200 ml influents solution equivalent to 400 mg ciprofloxacion.

Ciproflori is compatible with the following influence solutions.

Per provide the containing 200 ml influence on solutions:

Physiological sales most colution. Pilorge residence and colutions.

For how long should you use Ciproflor?

As a rule the averaged dustient of between the severity of the infection and the clinical and bacteriological course. In general, therapy should always be continued systematically for at least 3 days after the free has subsided and the clinical signs have disappeared. As a rule the averaged dustient of between them is:

**up to 7 days for infections of the kidneys, urinary tract and abdominal cavity,

**in patients with a compromised immer system, therapy should be continued for as long as the total white blood cell count is depressed (neutropenic phase).

**2-7-14 days for infections the market should be continued for at least 10 days because of the risk of late complications.

In steptococci infection sharply should be continued for at least 10 days because of the risk of late complications.

In steptococci infection special service of cystic (frostost caused by P, aeruginosa.

Anthrass

**On days of retearment for immediate therapy and for treatment of infections following inhalation of anthras pathogens.

10 - 14 days for acute innection episoposis or opera introdus accessor by a management of a days for acute innection episoposis or a construction of the control production of seitzures, a history of seizures, reduced blood flow in the brain, altered brain structure or a stroke in the past, Patients in this category are at risk of side selects in the central nervous system. In its category can be reduced to the past of the past, Patients in this category are at risk of side selects in the central nervous system. In clisical cases, profession-framed time the past, Patients in this category are at risk of side of the past, Patients of the past, Patients

in into account. 1 bottle of 100 ml infusion solution contains 900 mg sodium chloride (15.5 mmol).

is product must be taken final account. I some or to one memory that the definition and adolescent she allows, ciproflocacin, the active ingredient in Ciproton, is known to cause damage to the weightfinal memory that the control of the safety data of patients aped less than 18 who were mainly suffering from open injuried. Discovery the safety of the control of the safety data of patients aped less than 18 who were mainly suffering from open memory than the safety of the not for children aged less than 5 in genera Pregnancy
Ciprolon must not be used at any stage during pregnancy because no experience has been gained regarding use safety in pregnant women. Animal experiments have not produced any evidence of malformation of the foetus (exatogenic effects), but it is not entirely improbable that damage to cardiage may be caused in organisms which have not reached maturity.

Breast-feeding.

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It is also recommended on principle that Cipcolon should not be used while breast-feeding. Driving and operating machinery.

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Do not drive or operate power bods or machinery while stating his machiner, were when used correctly, his machiner may impair reaction speed so much that the ability to drive, operate machinery or work without a secure bothold may be reduced, of the patier may not be capable of doing these things at all. This applies particularly at the start of treatment, when the dose is increased, when stillott EFFECTS and the contraction with alcohol.

SIDE EFFECTS
Like all mediciones, Ciprolon can have side effects. The frequency is indicated as follows:
Frequently = 1 % to < 10 %
Cocasionally = 0.1 % to < 1 %
Rurely = 0.01 % to < 0.1 %
Ney rurely = 0.01 %

Rarely 20.01 % 20.01%

General Very rarely <0.01%

General Very rarely <0.01%

General Very rarely very representative for the succeptibility of disease-causing operations. A canadation of vessiones, Lung-term or repeated use of Ciproton can reduce the susceptibility of disease-causing before the initial infection has been eradicated.

All representatives of the initial infection has been eradicated. All representatives reactions (any elevents, e.g., facial, vessions and lampaged codema; dysproses rarging up to life-threatening shoot), in some instances after the first administration; pain (e.g., pain in the limbs, back, chairs.)

In the limbs, back, chairs are considered with serum sickness (with, for example, lever, welling of the lymph nodes. retarery. Allergic reactions, drug lever. In parsensibility reactions (anaphylactic/la

to fouch.

Very rarely: Insteady galt, increased intracranial pressure, psycholic reactions (psychological impairment with a ranging up to the point of self-endangement), in some cases after first use, impaired coordination, increased se increased muscin from, muscular frethiching.

Gastrointestinal tract Frequently: Nausea, diarrhose.

Conscientally: Vernifing, impaired depaired, abdominal pain, flatulence, loss of appetite.

Rarely: Jaundica, pseudomentoranous costis.

Cardroinsecular

Rarely: Papitations, general content of the content of the process o

Scrool Cocasionally: Increased levels of a certain type of white blood cell (eosinophilia), reduced levels of white blood cells (leus Parely: Reduced levels of red certain white blood cells (anameille, granulocytopenia) or blood patients (thrombooytos), shore of white blood cells (leuksoytosis) or blood plateits (thrombooytosis), shoreged blood coagulation factors increased levels of white blood cells (leuksoytosis) or blood plateits (thrombooytosis), shoreged blood coagulation factors increased levels or white blood cells (leuksoytosis) or blood plateits (thrombooytosis), shoreged blood coagulation factors are considered to the construction of the const

increased levels of white blood colls ((selsocytosis) or blood patients ((trombocytosis), changed blood coagulation factors (prothrontin) valued, a reduced and patient of the blood corpusation (learney) is anament, a reduction in all blood cells (parcytopenia, possi-very rarely; increased degratation; or a british hyper of white Blood cell with the possible symptoms of altwering, fever, bitsers in the control of the patient of the patie

Skids
Frequently: Skir rash.
Occasionally: Techniq (prurillus), raised, spotity skir rash (meculopapular exanthema), nettle rash (urticaria).
Razely: Light sensitivity with moderning of the skin (photosensitivity),
Very rarely: Punctate skin haemorrhages (petechiae), blister formation with accompanying haemorrhages (haemorrhagic bullae)
and mail nodules (appulse) with crust formation showing vacuotair involvemently (resultish), entytemen nodesum, rash on the skin and
mucous membranes close to the skin (fixed drug-induced exanthem), erythema exsudativum multiforme (minor) ranging up to severe
forms (Selvera-Schrisse syndrome), blister-like loss of the skin and oral/hasal mucosa (Lyell's syndrome).
Senserv organs:

nsory organs: casionally: Impaired sense of taste and smell. rely: Tinnitus, transient loss of hearing, particularly with high tones, visual resense of taste which is usually reversible after discontinuation of therapy, ry rarely: Loss of the sense of smell which is usually reversible after discor

Raiely: Inflammation of the kidney (intestitian apprima), transmin implementation of the kidney (intestitian apprima). The charactery inflammation of the kidney in patients with pre-existing liver damage, temporary effect on liver function with an increase in liver enzymetriansminase, alialized phosphatately ranging up to journdoor transient increase in the levels of urea, creatimine and bilinubin (a bile pigment) in the blood. Ranging in the blood are considered and the pigment in the blood and the pigment in the blood and the pigment in the blood are considered as the pigment of the blood or crystals in the urine (haematuria and crystalluria). Very ranging increased levels of foreign enzymes (arryfase, lipase).

Drug Inferenctions

Cyclorion must be administered separately unless compatibility with other infusion solutions/drug products has been confirmed. Visible signs of incompatibility include precipitation, cloudiness and discoloration of the solution. Incompatibility appears with all infusion solutions solutions that are phylytady or chemically unable at the pl H of Cyronion (e.g. perilicillins, heparin solutions), particularly when combined with solutions adjusted to an alkaline pH (pH of Ciproton infusion solution: 3,9-4,5).

proton/santhines
(init) (proton and theophylline (an asthma treatment) at the same time can lead to an unwanted increase in the concentration of
ophylline in the blood and, accordingly, to an increase in the rate of side effects caused by theophylline which, in isolated cases,
yet left-threatment or fails. If it is imperative to use both medicines at the same time, the theophylline concentration in the
od should be monitored and the disease should be reduced as required. There have been reports of raised concentrations of the
thinks derivatives califerine and periodyline (a medicine that promotes blood circulation) in the blood when these substances are
ministered at the same time as Ciproton.
Toolshorts-stretched arth-inflammatory drugs

robornion-steroidal and-inflammatory drugs
related to the control of the control

reconspropries of the state of kidney function associated with an increase in the concentration of creatinine in the blood ha been obe plotted cases when Ciprolon is taken at the same time as cyclosporin (a drug that suppresses the body's defence mechanism or creatinine concentration should be monitored closely (twice a week) if you are taking both medicines at the same time. noton/warfarin

ultaneous use of Ciprolon and warfarin (a drug that inhibits the coagulation of blood) may increase the action of warfarin.

on procened:
necid (a treatment for gout) affects the excretion of ciprofloxacin in urine (renal secretion). Simultaneous use of Ciprolon and necid increases the concentration of ciprofloxacin in the blood (serum).

opramide (a gastrointestinal medicine) accelerates the absorption of Ciprolon into the blood and causes the maximum ntration in the blood (plasma) to be reached more rapidly than usual. No effect on the bioavailability, Ciprolon in the human

ultaneous use of these two medicines may lead to a raised concentration of mexiletine in the body.

ion/phenytoin ted or lowered serum concentrations of phenytoin have been reported following the simultaneous use of these two me re have been reports that concomitant use of Ciprolon and diazepam delays the decomposition of diazepam in the body (reduced rance, extended half-life). Accordingly, careful monitoring of diazepam treatment is recommended.

ion/methotrexate taneous use of these two substances can lead to delayed excretion of methotrexate and thus to increased plasma levels of threxate. These patients should be carefully monitored, as this condition can lead to an increased risk of the reactions induced

coming a commission of expronovation with direptactor can read to a sayin reduction in the peak passing events attability (AUC) of ciprofloxacio. se inform your doctor or pharmacist if you are taking other medicines or have taken other medicines recently, ever they are

STOHAGE
Store below 30°C, protect from freezing. The solution is light sensiti
PRESENTATIONS

CIPROLON 200: Ciprofloxacin (as lactate) 200 mg in 100 ml/ vial Infusion bags
CIPROLON 400: Ciprofloxacin (as lactate) 400 mg in 200 ml/ infusic
Excipients: Lactic acid, Sodium Chloride, Hydrochloric acid, Water for Inje

drome), the additional burean or the social THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.

- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Manufactured by: Hikma Farmacêutica, Portugal For: HIKMA Pharmaceuticals, Amman-Jordan

Keep medicament out of the reach of children 2INCPRIJ-AE-04/2014