Zepro®

Tablets 250/500mg
Suspension 125/250mg

گولیاں ۲۵۰/۵۰۰ ملی گرام
زیپرو سسپینشن ۱۲۵/۲۵۰ ملی گرام

Composition:
Zepro® (Ciprofloxacin) is available for oral administration in film coated tablets
Zepro® 250mg Tablets
Each tablet contains.
Ciprofloxacin (as HCl) ..... 250mg.
Zepro® 500mg Tablets
Each Tablet contains:
Ciprofloxacin (as HCl) ..... 500mg.
Zepro® Suspension 125mg
Each 5ml after reconsitution contains:
Ciprofloxacin (as HCl) ..... 125mg.
Zepro® Suspension 250mg
Each 5ml after reconstitution contains:
Ciprofloxacin (as HCl) ..... 250mg.

Properties
Ciprofloxacin is a new drug from the quinolone group. These substances are also known as gyrase inhibitors.

Microbiology
Zepro® has a strong antibacterial action against a broad spectrum of bacteria. It prevents transcription by the chromosome (genetic material) of the information needed for the normal metabolism of bacteria. This leads to rapid decrease in the ability of bacterial reproduction.
Zepro® is also characterized by the fact that, as a results of its particular mode of action, it does not generally exhibit parallel resistance to any other antibiotic outside the gyrase inhibitor group. Therefore, **Zepro®** is highly effective against bacteria which are resistant, for example, to aminoglycosides, pencillins, cephalosporins, tetracycliens and other antibiotics.

Clinical Pharmacology
The absolute bioavailability of **Zepro®** is 70-80%. The maximum blood concentration is reached just 60-90 minutes after ingestion.
Zepro® 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:
Infections caused by pathogens which are sensitive to ciprfloxacin:
Infections:
- Respiratory tract. In the treatment of out patients with pneumonia due to pneumococcus, **Zepro®** should not be used as a first choice of drug. **Zepro®** can be regarded as an advisable treatment for pneumonias caused by klebsiella, Enterobacter, Proteus, Pesudomonas, Haemophilus, Branhamella, Legionella, and Staphylococcus.
- Middle ear (Otitis media), of the paranasal sinuses (sinusitis), especially if these are caused by gram negative organisms including Psedomonas and Staphylococcus.
- Eyes
- Kidneys and/or urinary tract
- Reproductive organs, including gonorrhea
- Abdominal cavity (e.g. bacterial infections of the gastro-intestinal tract, biliary tract, peritonitis).
- Skin and soft tissues
- Bones and joints
- Septicaemia
- Infections, or imminent risk of infection (prophylaxis). in immuno-compromised patients (e.g. those treated with ummuno-suppressants, patients with neutropenia).

Administration for selective intestinal decontamination in patients treated with immunosuppressant.
Zepro® has a bacterial action/ As a result of in-vitro investigations, the following pathogens may be regarded as sensitive to **Zepro®**
E. coli, Shigella, Samonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative). Providence, Morganella, Yersinia; Vibrio, Aeromonas, Plesiomonas, Paterurella, Harmophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella, Branhamella, Acimetobacter, Brucella; Staphylococcus, Streptococcus agalactiae, Listeria, Corynebacterium, Charmydia.
The following are sensitive in varying degrees:
Gardenella, Flavobacterium, Alcaligenes, Straptococcus faecalis, Streprococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, Mycoplasma horminis, Mycobacterium tuberculosis and Mycobacterium fortitum.
The following are, generally, resistant:
Streptococcus faecium, Ureaplasma urealyticum, Nocardia asteroides.
Anaerobes, apart from a few exception, very from being moderately sensitive (e.g. Peptococcus, Pepstreptococcus) to resistant (e.g. Bateroides).
Zepro® is not active against Treponema pallidum.

Contra-Indications
Zepro® should not be used where there is hypersensitivity to ciprofloxaxin or to other chemotherapeutic agents of the quinolone group.
Zepro® should not be prescribed to children, growing adolescents and pregnant or nursing women, as there is no evidence of its safety when used in these group and, on the basis of results from animal experiments, injury to the articular cartilage of an organism which is not fully grown cannot be completely ruled out, *animal* experiments have shown any evidence of teratogenic effects (malformations).

Restriction on use
Zepro® should be used with caution in the elderly. 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, altered brain structure or stroke).
Zepro® should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible central-nervous side effects.

Side-effects
The following side-effects have been observed.
- Effects on the gastro-intestinal tract
  Nausea, diarrhoea, vomiting, digestive disorders, abdominal pain, flatulance, anorexia.
  The doctor should be informed of any severe or persistent diarrhea occurring, during or after treatment, since these symptoms could conceala seious intestinal disorder (pseudomembranous colitis) requiring urgent treatment. In such cases, **Zepro®** should be discontinued and replaced by another appropriate drug (e.g. vancomycin orally 4x250 mg/day). Preparations which inhibit peristalsis are contra-indicated.
- Effects on the nervous system
  Dizziness, headache, tiredness, insomnia, agitation, trembling , very rarely peripheral paralgesia, sweating, unsteady gait, convulsions, anxiety states, nightmares, confusion, depressions, hallucinations, impaired taste and smell, visual disturbances (e.g. Double vision, colour vision). In some instances, theses reactions occurred after the first administration of **Zepro®** . In these cases, **Zepro®** has to be discontinued and the doctor should be informed immediately.
- Hypersensitivity reactions
  Skin reactions, e.g. Rashes.
  Very rarely.
- Pruritus, drug fever
- Anaphylactic/anaphylactoid reactions (e.g. facial, vascular and laryngeal oedema; dyspnoea progressing to life-threatening shock). in these cases **Zepro®** has to be discontinued, medical treatment (e.g treatment for shock) is required.
- Punctuate skin haemorrhages (pelechiae), blister formation with accompanying haemorrhages (haemorrhagic bullae) and small nodules (papules) with crust formation showing vascular involvement (vasculitis), Stevens-Johnson syndrome, interstitial nephritis, hepatitis: very rarely major liver disorders including hepatic necrosis.
- Effects on the cardiovascular system
  Very rarely: tachycardia, hot flushes, migraine, fainting.
- Other
  Very rarely: joint pains, general feeling of weakness, muscular pains, tendovaginitis, mild photosensitivity, transient impairment in kidney function, including transient kidney failure, tinnitus transitory impairment of hearing, especially at high frequencies.
- Effects on blood and blood constituents
  Eosinophilia, leucocytopenia, leucocytosis, anemia; very rarely: thrombocytopenia, thrombocytosis, altered prothrombin levels.
- Effect on laboratory values/urine deposits
  There may be a transient rise in the transaminase and alkaline phosphatase levels, or cholestatic jaundice may occur particularly in patients with previous liver damage: transient increase in serum urea, creatinine and bilirubin levels, hyperglycaemia; in individual cases; crystalluria and haematuria.

Warning to drive:
Even when taken as prescribed, this drug can after patients responsiveness, impairing the ability to drive or operate machinary. This is even more applicable when the drug is taken in conjunction with alcohol.

Interactions
Drugs which effect the acidity of the stomach (antacids) containing (absorption) of **Zepro®** or magnesium hydroxide reduce the uptake (absorption) of **Zepro®** . Consequently, **Zepro®** should be taken either 1-2 hours before, or at least 4 hours after the antacid. This restriction does not apply to antacids which do not contains aluminum or magnesium hydroxide (e.g. H2-receptor blockers)
The simultaneous administration of **Zepro®** and heophylline can lead to an unwanted increase in the serum theophylline concentration, thereby producing theophyline-induced side-effects. If the concomitant administration of these two drugs is unavailable, the serum concentration of theophylline should be checked and its dosage reduced accordingly. Animal experiments have indicated that the combination of very high doses of quinolones (gyrase inhibitors) with certain nonsteroidol anti-inflamatory drugs (e.g. fenbufen, but not acetylsalicylic acid) can lead to convulsions. However, these interactions have not been observed in patients taking **Zepro®** .
A transient rise in the concentration of serum creatinine was observed when **Zepro®** and Cyclosporin were administered simultaneously. Therefore, it is necessary to control the serum creatinine concentrations in these patients frequently (twice a week).

Dosage and Administration
The recommended adult dosage for acute sinusitis is 500-mg every 12 hours.
Lower respiratory tract infections may be treated with 500-mg every 12hours. For more severe or complicated infections, a dosage of 750-mg may be given every 12 hours.
Severe/complecated urinary tract infections or urinary tract infections caused by organisms not highly susceptible to Ciprofloxacin may be treated with 500-mg every 12 hours. For other mild/moderate urinary infections, the usual adult dosage is 250-mg every 12 hours.
The recommended adult dosage for chronic bacterial prostatitis is 500-mg every 12 hours.
The recommended adult dosage for oral sequential therapy of complicated intra-abdiminal infections is 500-mg every 12 hours, (To provide appropriate anaerobic activity, metroidazole should be given according to product labeling).
Skin and skin structure infections and bone and joint infections may be treated with 500-mg every 12 hours. For more severe or complicated infections, a dosage of 750-mg may be given every 12 hours.
The recommended adult dosage for infections diarrhoea or typhoid fever is 500-mg every 12 hours. For the treatment of uncomplicated urethral and cervical gonococcal infections, a single 250-mg dose is recommended

DOSAGE GUIDELINES

Infections	Type of Severity	Unit Dose	Frequency	Usual Durations"/"
Acute Sinusitis	Mild/Moderate	500-mg	q 12h	10 Days
Lower Respiratory Tract	Mild/Moderate Severe/Complicated	500-mg 750-mg	q 12h q 12h	7 to 14 Days 7 to 14 Days
Urinary Tract	Acute Uncomplicated Mild/Moderate Severe/Complicated	500-mg 250-mg 500-mg	q 12h q 12h q 12h	3 Days 7 to 14 Days 7 to 14 Days
Chronic Bacterial Prostatitis	Mild/Moderate	500-mg	q 12h	28 Days
Intra-Abdominal	Complicated	500-mg	q 12h	7 to 14 Days
Skin and Skin Structure	Mild/Moderate Severe/Complicated	500-mg 750-mg	q 12h q 12h	7 to 14 Days 7 to 14 Days
Bone and Joint	Mild/Moderate Severe/Complicated	500-mg 750-mg	q 12h q 12h	>/=4 to 6 weeks >/=4 to 6 weeks
Infections Diarrhea	Mild/Moderate/Severe	500-mg	q 12h	5 to 7 Days
Typhoid Fever	Mild/Moderate	500-mg	q 12h	10 Days
Urethral and Cervical Gonococcal Infections	Uncomplicated	250-mg	Single dose	Single dose

* used in conjunction with metronidazole

**/* Generally ciprofloxacin should be continued for at least 2 days after the signs and symptoms of infections have disappeared.

PEDIATRIC DOSAGE GUIDELINES

Infections	Dose	Frequency	Usual Duration
(Complicated urinary tract or Pyelonephritis (patients from 1 to 17 years of age)	10 to 20 mg/kg (maximum 750 mg per dose, not be exceed even in patients weighing > 51kg)	Twice daily	10-21 days
Inhalational Anthrax (Post-Exposure)	15 mg/kg (maximum 500 mg per dose)	Twice daily	60 days
Infections Diarrhea (Dysentery)	10 to 15 mg/kg per dose (maximum 500 mg/dose)	Twice daily	5 days
Typhoid fever	10 to 15 mg/kg per dose (maximum 500 mg/dose)	Twice daily	5 days

Use of Ciprofloxacin in Children. Use is only warranted if benefits outweight the risks of arthopathy. It should be used in children (less than 1 year) only for infections listed in the indications

The duration of treatment depends upon the severity of infection Generally Ciprofloxacin should be continued for at least 2 days after the signs and symptoms of infections have disappeared. The usual duration is 7 to 14 days; however, for severe and complicated infections more prolonged therapy may be required. Bone and joint infections may require treatment for 4 to 6 weeks or longer. Chronic Bacterial Prostatitis should be treated for 28 day. Infectious diarrhea may be treated for 5-7 days. Typhoid fever should be treated for 10 days

Restricted kidney and liver dunction
1. Restricted kidney function
   Ceatinine clearance
   <20ml.min - Serum creatinine > 3mg/100ml:
   half the normal dose twice daily or
   the full normal dose once a day
2. Restricted kidney function + haemodialysis
   Dosage as for 1. On dialysis days after dialysis.
3. Restricted liver function
   No dosage adjustment required.
4. Restricted kidney and liver function levels
   Dosage adjustment as for 1., possibly check **Zepro®** serum levels.

Administration
The tablets should be taken whole with a little fluid. They do not need to be taken at mealtimes. Absorption of the drug is accelerated if taken on and empty stomach.

Administration Period
The treatment period depends upon the severity and the clinical course of the illness and bacteriological results. Essentially, treatment should be continued for at least 3days after the temperature has returned to normal and/or the clinical symptoms have disappeared. Average treatment period: 1 day for acute gonorrhea, up to 7 days for infections of the kidneys, urinary tract and abdominal cavity, throughout the entire neutropenic phase in immuno compromised patients, a maximum of 2 months for osteomayelitis and 7-14 days for all other infections.
Treatment should continue for a minimum of 10 days in streptococcal infections owing to the risk of late complications.

Warning
Zepro® should not be administered after the expiry date.
Keep medicine out of the reach of children.

Presentation:
Zepro® 250mg Tablets
10 Film coated Tablets in Alu-Alu blister pack.
Zepro® 500mg Tablets
10 Film coated Tablets in Alu-Alu blister pack.
Zepro® Suspension 125mg
60ml Suspension filled in amber coloured bottles.
Zepro® Suspension 250mg
60ml Suspension filled in amber bottles.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی دسترس سے دور رکھیں۔
سورج کی روشنی سے بچائیں۔

دوا تیار کرنے کا طریقہ:
بوتل کو ہلا کر اس میں موجود پاؤڈر کو بوتل کی دیواروں سے علیحدہ کر لیں ڈبہ میں ساتھ دیے گئے پیمانے کی مدد سے ۲۰ (بیس) ملی لیٹر تازہ اُبلا ہوا ٹھنڈا پانی ڈال کر بوتل کو اچھی طرح ہلائیں۔
۲۰ (بیس) ملی لیٹر تازہ اُبلا ہوا ٹھنڈا پانی مزید ڈال کر بوتل کو اس طرح ہلائیں کہ یک جان سسپینشن تیار ہو جائے۔
خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف پینے کے لئے ہے۔
ہدایات: استعمال سے قبل بوتل کو اچھی طرح ہلائیں اور استعمال کے بعد ڈھکن کو اچھی طرح بند کر دیں۔
بچوں کی پہنچ سے دور رکھیں۔ منجمد ہونے سے بچائیں۔
دوا کو دھوپ۔ گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ یا اس سے کم درجہ حرارت پر رکھیں۔
تیار کردہ سسپینشن کو ریفریجریٹر میں 2-8 ڈگری سینٹی گریڈ کے درمیان رکھیں۔
اور دوا تیار کرنے کے بعد ۱۴ دن کے اندر استعمال کر لیں۔

Manufactured By:
Dyson Research Laboratories (Pvt.) LTD.
28th-KM Ferozepur Road, Lahore-Pakistan
ISO 9001:2015 Certified Company