

chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI).

Limitation/Restriction of use

Fluoroquinolones should be reserved for use in patients who have no other treatment options available for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI).

SIDE EFFECTS:

The symptomatic adverse reactions produced by ciprofloxacin HCl are more or less tolerable and if they become severe, they can be treated symptomatically, these include dizziness, headache, nausea, vomiting, diarrhoea, nervousness, tremors, rashes, urticaria, pruritus, photosensitivity, elevation of liver enzymes, eosinophilia and increased intracranial pressure.

Worsening of symptoms of Myasthenia Gravis/exacerbation of Myasthenia Gravis.

Peripheral neuropathy:

This serious nerve damage potentially caused by fluoroquinolones may occur soon after these drugs are taken and may be permanent. If a patient develops symptoms of peripheral neuropathy, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolone antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk.

DRUG INTERACTIONS:

Ciprofloxacin HCl is known to interact with other drugs like aluminium hydroxide and oxide, azlocillin (Na), caffeine, calcium carbonate, chloramphenicol, cyclosporine A, drazepam, foscarnet(Na), rifampicin, succraliate, theophylline, warfarin(Na), alprazolam, bromazepam, zinc sulphate, zolmitriptan, zolpidem (Tartrate), estazolam, ropinirole HCl.

These interactions are sometimes beneficial and sometimes may pose threats to life. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

STABILITY:

See expiry on the pack

PRESENTATION:

Suprox 250mg tablets Blister pack of 10's
Suprox 500mg tablets Blister pack of 10's

INSTRUCTIONS:

Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30° C
Improper storage may deteriorate the medicine.

ہدایات:

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کو ۱۵-۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:

Platinum
Pharmaceuticals (Pvt) Ltd.
A-20, North Western Industrial Zone,
Bin Qasim, Karachi-75020, Pakistan.

QAR No. AW19-0491

Suprox

(Ciprofloxacin HCl)

Tablet 250mg/ 500mg

سپروکس
(سپرولفاکساسین ہائیڈروکلورائیڈ)
۲۵۰/۵۰۰ ملی گرام گولیاں

COMPOSITION:

Suprox 250mg Tablets

Each film-coated tablet contains:
Ciprofloxacin HCl USP equivalent to Ciprofloxacin.....250mg

Suprox 500mg Tablets

Each film-coated tablet contains:
Ciprofloxacin HCl USP equivalent to Ciprofloxacin.....500mg

PROPERTIES:

Ciprofloxacin HCl is of semi-synthetic origin and belongs to quinolone carboxylic acid. It belongs to DNA gyrase inhibitor pharmacological group on the basis of mechanism of action and also classified in antibiotics pharmacological group. Ciprofloxacin HCl is effective against many gram-positive and gram-negative bacteria, including some strains resistant to penicillins, cyclosporins and aminoglycosides.

INDICATIONS AND USAGE:

Suprox is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions and patient populations listed below:

ADULTS:

Urinary Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, *Staphylococcus saprophyticus*, or *Enterococcus faecalis*.

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Acute Uncomplicated Cystitis in females caused by *Escherichia coli* or *Staphylococcus saprophyticus*.

Chronic Bacterial Prostatitis caused by *Escherichia coli* or *Proteus mirabilis*.

Lower Respiratory Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, or *Streptococcus pneumoniae*.

Also, *Moraxella catarrhalis* for the treatment of acute exacerbations of chronic bronchitis.

NOTE: Although effective in clinical trials, ciprofloxacin HCl is not a drug of first choice in the treatment of presumed or confirmed pneumonia secondary to *Streptococcus pneumoniae*.

Acute Sinusitis caused by *Haemophilus influenzae*, *Streptococcus pneumoniae*, or *Moraxella catarrhalis*.

Skin and Skin Structure Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* (Methicillin-susceptible), *Staphylococcus epidermidis*, or *Streptococcus pyogenes*.

Bone and Joint Infections caused by *Enterobacter cloacae*, *Serratia marcescens*, or *Pseudomonas aeruginosa*.

Complicated Intra-Abdominal Infections (Used in combination with metronidazole) caused by *Escherichia coli*, *Pseudomonas aeruginosa*, *Proteus mirabilis*, *Klebsiella pneumoniae*, or *Bacteroides fragilis*.

Infectious Diarrhoea caused by *Escherichia coli* (Enterotoxigenic strains), *Campylobacter jejuni*, *Shigella boydi*, *Shigella dysenteriae*, *Shigella flexneri* or *Shigella sonnei* when antibacterial therapy is indicated.

Typhoid Fever (Enteric Fever) caused by *Salmonella typhi*.

NOTE: The efficacy of ciprofloxacin HCl in the eradication of the chronic typhoid carrier state has not been demonstrated.

Uncomplicated Cervical and Urethral Gonorrhoea due to Neisseria gonorrhoeae

DOSAGE AND ADMINISTRATION: Unless otherwise prescribed, the following guideline doses are recommended:

ADULTS

Urinary tract infections

- Acute uncomplicated.....250mg twice daily, 3 days
- Mild/Moderate.....250mg twice daily, 7 to 14 days
- Severe/Complicated.....500mg twice daily, 7 to 14 days

Chronic bacterial prostatitis

- Mild/Moderate.....500mg twice daily, 28 days

Lower respiratory tract infections

- Mild/Moderate.....500mg twice daily, 7 to 14 days
- Severe/Complicated.....750mg twice daily, 7 to 14 days

Acute sinusitis

- Mild/Moderate.....500mg twice daily, 10 days

Skin and skin structure infections

- Mild/Moderate.....500mg twice daily, 7 to 14 days
- Severe/Complicated.....750mg twice daily, 7 to 14 days

Bone and joint infections

- Mild/Moderate.....500mg twice daily, 4 to 6 weeks
- Severe/Complicated.....750mg twice daily, 4 to 6 weeks

Intra-abdominal infections

- Complicated.....500mg twice daily, 7 to 14 days

Infectious diarrhoea

- Mild/Moderate/Severe.....500mg twice daily, 5 to 7 days

Typhoid fever

- Mild/Moderate.....500mg twice daily, 10 days

Urethral and cervical

Gonococcal infections

- Uncomplicated.....250mg single dose, 1 day

Duration of Use:

Duration of treatment depends on severity of the illness and on the clinical and biological course.

OR

As directed by the physician

CONTRAINDICATIONS:

Suprox (Ciprofloxacin HCl) is contraindicated in persons with a history of hypersensitivity to Ciprofloxacin HCl or any member of the quinolone class or antimicrobial agents.

WARNINGS:

There is risk of serious and occasionally fatal hypersensitivity reactions after multiple doses. Treatment should be discontinued at the first appearance of skin rash, jaundice, or any other sign of hypersensitivity, and supportive measures should be instituted. Risk of *Clostridium difficile*-associated diarrhea (CDAD) should be considered.

SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS

Fluoroquinolones, including (Ciprofloxacin), have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue (Ciprofloxacin) immediately and avoid the use of fluoroquinolones, including (Ciprofloxacin) in patients who experience any of these serious adverse reactions. Fluoroquinolones, including (Ciprofloxacin) may exacerbate muscle weakness in patients with myasthenia gravis. Avoid (Ciprofloxacin) in patients with known history of myasthenia gravis. As fluoroquinolones including (Ciprofloxacin) have been associated with serious adverse reactions, reserve (Ciprofloxacin) for use in patients who have no alternative treatment options for the following indications:

- Acute exacerbation of chronic bronchitis
- Acute uncomplicated cystitis
- Acute sinusitis
- Acute uncomplicated cystitis

Pregnant Women:

The safety and effectiveness of ciprofloxacin HCl in pregnant and lactating women have not been established.

Paediatrics:

Ciprofloxacin HCl should be used in paediatric patients (Less than 18 years of age) only for infections listed in the indications section. An increased incidence of adverse events compared to controls including events related to joints and/or surrounding tissues, has been observed.

PRECAUTIONS:

In epileptics and in patients who have suffered from previous CNS-disorders (e.g. Lowered convulsion threshold, previous history of convulsions, reduced cerebral blood flow, altered brain structure or stroke), Suprox should only be used where the benefits of treatment exceed the risks, since these patients are endangered because of possible Central Nervous System side effects

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