SUPRAX®

(Cefixime as trihydrate)

ACTION

Suprax developed by Astellas research laboratories is a broad spectrum semisynthetic cephalosporin antibiotic for oral administration. The bactericidal action of Suprax results from inhibition of cell-wall synthesis. Suprax is highly beta-lactamase stable and as a result, many organisms resistant to penicillins and some cephalosporins, due to the presence of beta-lactamases, are susceptible to Suprax.

INDICATIONS

Suprax has been shown to be active against most strains of the following Gram-positive and Gram-negative organisms:

Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Haemophilus influenzae, Haemophilus parainfluenzae, Moraxella (Branhamella) catarrhalis, Escherichia coli, Proteus mirabilis, Proteus vulgaris, Neisseria gonorrhoeae, Klebsiella pneumoniae, Klebsiella oxytoca, Pasteurella multocida, Providencia species, Salmonella species, Shigella species, Citrobacter diversus, Serratia marcescens.

Suprax is indicated in the treatment of the following:

- Pharyngitis, tonsillitis and sinusitis.
- Acute bronchitis and acute exacerbations of chronic bronchitis.
- Otitis media.
- Uncomplicated urinary tract infections.
- Uncomplicated urethral or cervical gonorrhea.
- Bacterial gastroenteritis.

DOSAGE AND ADMINISTRATION

Adults:

The recommended dose of Suprax is 400 mg daily. This may be given as a 400 mg capsule once daily, or as a solution of Suprax D 400 mg dispersible tablets, or as a 200 mg capsule every 12 hours.

For the treatment of uncomplicated urethral or cervical gonococcal infections, a single oral dose of 400 mg is recommended.

Children:

The recommended dose is 8 mg/kg/day of suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.

Patient weight (kg)	Dose/day (mg)	Dose/day (ml)	Dose/day (teaspoonful)
6.25	50	2.5	0.5
12.5	100	5.0	1.0
18.75	150	7.5	1.5
25	200	10.0	2.0

Children weight more than 50 kg or older than 12 years should be treated with the recommended adult dose.

Renal impairment: Suprax may be administered in the presence of impaired renal function as follows:

Creatinine clearance	Dose
≥ 60 ml/min	Standard dose (400 mg daily)
21-60 ml/min	75% of the standard dose (300 mg daily)
≤ 20 ml/min	Half the standard dose (200 mg daily)

Reconstitution: Invert bottle and shake powder loose. Add the volume of water stated on the bottle label and outer box in two portions shaking after each addition until a homogeneous suspension is achieved. When first reconstituted allow to stand for five minutes to ensure full dispersion.

Suprax D 400 -dispersible tablets may be taken as a whole tablet or may be dissolved in a generous amount of liquid and taken orally. Dispersible tablets must only be dissolved in water, not in milk; or juice; and without regards to meals. The ready to use solution should be used immediately after preparation.

CONTRAINDICATIONS

Cefixime is contraindicated in patients with known allergy to cephalosporin group of antibiotics.

WARNINGS

Before therapy with cefixime is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefixime occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines and airway management, as clinically indicated. Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime. Antibiotics, including cefixime, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs. Treatment with broad spectrum antibiotics, including cefixime, alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of severe antibiotic-associated diarrhea including pseudomembranous colitis. Pseudomembranous colitis has been reported with the use of cefixime and other broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider this diagnosis in patients who develop diarrhea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment and may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, management should include fluids, electrolytes, and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by C. difficile. Other causes of colitis should be excluded.

PRECAUTIONS

The possibility of the emergence of resistant organisms which might result in overgrowth should be kept in mind, particularly during prolonged treatment. In such use, careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken. The dose of cefixime should be adjusted in patients with renal impairment as well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully.

Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. Cephalosporins may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated.

SIDE EFFECTS

Most of adverse reactions observed in clinical trials were of a mild and transient nature. Five percent (5%) of patients in the U.S. trials discontinued therapy because of drug-related adverse reactions. The most commonly seen adverse reactions in U.S. trials of the tablet formulation were gastrointestinal events, which were reported in 30% of adult patients on either the BID or the QD regimen. Clinically mild gastrointestinal side effects occurred in 20% of all patients, moderate events occurred in 9% of all patients and severe adverse reactions occurred in 2% of all patients. Individual event rates included diarrhea 16%, loose or frequent stools 6%, abdominal pain 3%, nausea 7%, dyspepsia 3%, and flatulence 4%. The incidence of gastrointestinal adverse reactions, including diarrhea and loose stools, in pediatric patients receiving the suspension was comparable to the incidence seen in adult patients receiving tablets.

These symptoms usually responded to symptomatic therapy or ceased when cefixime was discontinued.

Several patients developed severe diarrhea and/or documented pseudomembranous colitis, and a few required hospitalization. The following adverse reactions have been reported following the use of cefixime. Incidence rates were less than 1 in 50 (less than 2%), except as noted above for gastrointestinal events.

Gastrointestinal: Diarrhea, loose stools, abdominal pain, dyspepsia, nausea, and vomiting. Several cases of documented pseudomembranous colitis were identified during the studies. The onset of pseudomembranous colitis symptoms may occur during or after therapy.

Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities), skin rashes, urticaria, drug fever, pruritus, angioedema, and facial edema. Erythema multiforme, Stevens-Johnson syndrome, and serum sickness-like reactions have been reported.

Hepatic: Transient elevations in SGPT, SGOT, alkaline phosphatase, hepatitis, jaundice.

Renal: Transient elevations in BUN or creatinine, acute renal failure.

Central Nervous System: Headaches, dizziness, seizures.

Hemic and Lymphatic Systems: Transient thrombocytopenia, leukopenia, neutropenia, and eosinophilia. Prolongation in prothrombin time was seen rarely.

Abnormal Laboratory Tests: Hyperbilirubinemia.

Other: Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.

In addition to the adverse reactions listed above which have been observed in patients treated with cefixime, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Adverse reactions: Allergic reactions, superinfection, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, and colitis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

Abnormal Laboratory Tests: Positive direct Coombs test, elevated LDH, pancytopenia, agranulocytosis.

OVERDOSAGE

Gastric lavage may be indicated; otherwise, no specific antidote exists. Cefixime is not removed in significant quantities from the circulation by hemodialysis or peritoneal dialysis. Adverse reactions in healthy adult volunteers receiving single doses up to 2 g of Cefixime did not differ from the profile seen in patients treated at the recommended doses.

STORAGE

Capsules, Tablets: Store between 15-25°C.

Suspension: Store dry powder and reconstituted suspension between 15-25°C.

PRESENTATIONS

Capsules

SUPRAX 400: Cefixime (as trihydrate) USP 400 mg/capsule

SUPRAX 200: Cefixime (as trihydrate) USP 200 mg/capsule

Excipients: Colloidal Silicon Dioxide, Magnesium Stearate, Carboxymethyl Cellulose Calcium.

Dispersible Tablets

SUPRAX D 400: Cefixime (as trihydrate) USP 400 mg/tablet

Excipients: Microcrystalline Cellulose, Hydroxypropyl Cellulose, Povidone, Orange Yellow S (E110), Saccharin Calcium, Colloidal Anhydrous Silica, Strawberry Powder Flavour, Magnesium Stearate.

Suspension

SUPRAX100: Cefixime (as trihydrate) USP 100 mg/5ml*

Excipients: Xanthan Gum, Sodium Benzoate, Strawberry Powder Flavor, Sucrose.

* After reconstitution

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.

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Keep medicament out of the reach of children

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