SECURE

COMPOSITION:

CAPSULES
Secure 200mg capsules:
Each capsule contains:
Cefixime (U.S.P) ……. 200mg
(as trihydrate)
Secure 400mg capsules:
Each capsule contains:
Cefixime (U.S.P) ……. 400mg
(as trihydrate)
Product conforms to the Manufacturer's Specifications.

SUSPENSION
Secure 100mg/5ml Powder for Suspension
Each 5ml contains:
Cefixime (U.S.P) …..100mg
(as trihydrate)
Secure DS 200mg/5ml Powder for Suspension
Each 5ml contains:
Cefixime (U.S.P) …..200mg
(as trihydrate)
Product conforms to the U.S.P Specifications.

DESCRIPTION:

Cefixime is a semisynthetic, cephalosporin antibacterial for oral administration. Chemical Formula is $C_{16}H_{15}N_5O_7S_2.3H_2O$

MICROBIOLOGY:

Mechanism of Action
Cefixime is a semisynthetic cephalosporin antibacterial drug. As with other cephalosporins, the bactericidal action of Cefixime results from inhibition of cell wall synthesis. Cefixime is stable in the presence of certain beta-lactamase enzymes. As a result, certain organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to Cefixime.
Antimicrobial Activity: Cefixime has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections.
Gram-positive Bacteria: Streptococcus pneumoniae & Streptococcus pyogenes.
Gram-negative Bacteria: Escherichia coli, Haemophilus influenzae, Moraxella catarrhalis, Neisseria gonorrhoeae & Proteus mirabilis.
PHARMACOKINETICS
Only 40-50% of an oral dose of Cefixime is absorbed from the gastrointestinal tract, whether taken before or after meals, although the rate of absorption may be decreased in the presence of food. Cefixime is better absorbed from oral suspension than capsules. Absorption is fairly slow; peak plasma concentrations of 2 to 3 micrograms/mL and 3.7-4.6 micrograms/mL have been reported between 2-6 hours after single doses of 200 and 400mg, respectively. The plasma half-life is usually about 3 to 4 hours and may be prolonged when there is renal impairement. About 65% of Cefixime is bound to plasma proteins. Cefixime crosses the placenta. Relatively high concentrations may be achieved in bile and urine. About 20% of an oral dose (or 50% of an absorbed dose) is excreted unchanged in the urine within 24 hours. Up to 60% may be eliminated by normal mechanisms; there is no evidence of metabolism but some is probably excreted into faeces from bile. It is not substantially removed by dialysis.

INDICATIONS:

Cefixime (Secure) is a cephalosporin antibacterial drug indicated in the treatment of adults and pediatric patients six months of age or older with the following infections when caused by susceptible isolates of the designated bacteria:

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Uncomplicated Urinary Tract Infections: Uncomplicated Urinary Tract Infections caused by Escherichia coli and Proteus mirabilis.
Otitis Media: Otitis Media caused by Haemophilus influenzae, Moraxella catarrhalis, and Streptococcus pyogenes. (Efficacy for Streptococcus pyogenes in this organ system was studied in fewer than 10 infections.)
Note: For patients with otitis media caused by Streptococcus pneumoniae, overall response was approximately 10% lower for Cefixime than for the comparator.
Pharyngitis and Tonsillitis: Pharyngitis and Tonsillitis caused by Streptococcus pyogenes.
Cefixime (Secure) is generally effective in the eradication of Streptococcus pyogenes from the nasopharynx; however, data establishing the efficacy of Cefixime (Secure) in the subsequent prevention of rheumatic fever is not available.
Acute Exacerbations of Chronic Bronchitis: Acute Exacerbations of Chronic Bronchitis caused by Streptococcus pneumoniae and Haemophilus influenzae.
Uncomplicated Gonorrhea (cervical/urethral): Uncomplicated Gonorrhea (cervical/urethral) caused by Neisseria gonorrhoeae (penicillinase-and non-penicillinase-producing isolates).

DOSAGE & ADMINISTRATION:

Adults
The recommended dose of Cefixime (Secure) is 400 mg daily. This may be given as a 400 mg capsule daily. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended. It may be administered without regard to food.
In the treatment of infections due to Streptococcus pyogenes, a therapeutic dosage of Cefixime (Secure) should be administered for at least 10 days.
Pediatric Patients (6 months or older)
The recommended dose is 8 mg/kg/day of the 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.

PEDIATRIC DO SAG E CHART:
Doses are suggested for each weight range and rounded for ease of administration

		Cefixime (Secure) for Oral Suspension	
		100 mg/5 mL	200 mg/5 mL
Patient Weight (kg)	Dose/Day (mg)	Dose/Day (mL)	Dose/Day (mL)
5 to 7.5	50	2.5	—
7.6 to 10	80	4	2
10.1 to 12.5	100	5	2.5
12.6 to 20.5	150	7.5	4
20.6 to 28	200	10	5
28.1 to 33	250	12.5	6
33.1 to 40	300	15	7.5
40.1 to 45	350	17.5	9
45.1 or greater	400	20	10

CONTRAINDICATIONS:

Cefixime (Secure) is contraindicated in patients with known allergy to Cefixime or other cephalosporins.

PRECAUTIONS:

Hypersensitivity Reactions: Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of Cefixime. 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.
Clostridium Difficile-Associated Diarrhea: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefixime (Secure), and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.
Dose Adjustment In Renal Impairment: The dose of Cefixime (Secure) 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.
Coagulation Effects: Cephalosporins, including Cefixime (Secure), may be associated with a fall in prothrombin activity. Prothrombin time should be monitored in patients at risk and exogenous Vitamin K administered as indicated.
Development Of Drug-Resistant Bacteria: Prescribing Cefixime (Secure) in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

PREGNANCY & LACTATION:

Pregnancy: Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 40 times the human dose and have revealed no evidence of harm to the fetus due to Cefixime. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
Nursing Mothers: It is not known whether Cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug.

DRUG-DRUG INTERACTIONS:

Carbamazepine: Elevated Carbamazepine levels have been reported in postmarketing experience when Cefixime (Secure) is administered concomitantly.
Warfarin & Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when Cefixime (Secure) is administered concomitantly.
Drug/Laboratory Test Interactions: A false-positive reaction for ketones in the urine may occur with tests using Nitroprusside but not with those using Nitroferricyanide. The administration of Cefixime may result in a false-positive reaction for glucose in the urine. A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.

ADVERSE DRUG REACTIONS:

The following adverse reactions have been reported following the use of Cefixime (Secure):
Gastrointestinal: Several cases of documented pseudomembranous colitis were identified in clinical trials. 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.

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Renal: Transient elevations in BUN or creatinine, acute renal failure.
Central Nervous System: Headaches, dizziness, seizures.
Hemic and Lymphatic System: Transient thrombocytopenia, leukopenia, neutropenia, prolongation in prothrombin time, elevated LDH, pancytopenia, agranulocytosis, and eosinophilia.
Abnormal Laboratory Tests: Hyperbilirubinemia.
Other Adverse Reactions: Genital pruritus, vaginitis, candidiasis, toxic epidermal necrolysis.
Adverse Reactions Reported for Cephalosporin-class Drugs
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.

OVER DOSAGE:

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.

INSTRUCTIONS:

Store in a cool & dry place below 25ºC.
Protect from light, heat and moisture.
Keep out of reach of children.

PRESENTATION:

Capsules
Secure 200mg capsules are available in a blister pack of 7's.
Secure 400mg capsules are available in a blister pack of 7's.
Suspension
Secure 100mg/5ml powder for suspension is available in a bottle pack of 30ml.
Secure 100mg/5ml powder for suspension is available in a bottle pack of 60ml.
Secure DS 200mg/5ml powder for suspension is available in a bottle pack of 30ml.