Cefiscot

Capsules*, Suspension* & DS Suspension*

سیفی سکاٹ

کیپسولز، سسپینشن اور ڈی ایس سسپینشن

COMPOSITION:

Each capsule contains: Cefixime BP/USP.....400 mg

Each 5 ml of Cefiscot Suspension contains: Cefixime BP/USP.....100 mg (When prepared as directed)

Each 5 ml of Cefiscot DS Suspension contains: Cefixime BP/USP.....200 mg (When prepared as directed)

DESCRIPTION: Cefixime is a semisynthetic, cephalosporin antibiotic for oral administration. Chemically, it is (6*R*,7*R*)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7ż-(*Z*)-[*O*-(carboxymethyl)oxime] trihydrate. Molecular weight is 507.50 as the trihydrate. Chemical formula is $C_{16}H_{15}N_5O_7S_2.3H_2O$.

PHARMACOLOGY: *Pharmacodynamics:* Bactericidal action of cefixime results from inhibition of cell-wall synthesis. Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime. *Pharmacokinetics***:** Cefixime, given orally, is about 40-50% absorbed whether administered with or without food. An average peak serum concentration of a single 400 mg capsule is approximately 3.7 mcg/ml. The oral suspension produces average peak concentrations approximately 25-50% higher than the capsules. Peak serum concentrations occur between 2 and 6 hours following oral administration of a single 400 mg capsule of cefixime and between 2 and 5 hours following a single administration of 200 mg of oral suspension. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. Serum protein binding is concentration independent and is approximately 65%. The serum half-life of cefixime in healthy subjects is independent of dosage form and averages 3-4 hours but may range up to 9 hours in some normal volunteers. *Microbiology:* Cefixime has been shown to be active against most gram-positive (*Streptococcus pneumoniae*, *Streptococcus pyogenes*) and gram-negative (*Haemophilus influenzae*, *Moraxella catarrhalis*, *Escherichia coli*, *Proteus mirabilis*, and *Neisseria gonorrhoeae*) organisms both *in vitro* and in clinical infections. Cefixime, though active *in vitro* against certain other strains of gram-positive and gram-negative organisms, has not been able to establish its clinical efficacy against them.

INDICATIONS: Cefiscot (Cefixime) Capsules & Suspension are indicated in the treatment of following infections when caused by susceptible strains of the designated microorganisms:

- **Uncomplicated Urinary Tract Infections** caused by *Escherichia coli* and *Proteus mirabilis*.
- **Otitis Media** caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella catarrhalis*, (most of which are beta-lactamase positive) and *S. pyogenes.*
- **Pharyngitis & Tonsillitis** caused by *S. pyogenes*.
- **Acute Bronchitis & Acute Exacerbations of Chronic Bronchitis** caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* (beta-lactamase positive and negative strains).
- **Uncomplicated Gonorrhoea** (cervical/urethral) caused by *Neisseria gonorrhoeae* (penicillinase and non-penicillinase-producing strains).
- **Gastrointestinal Tract Infections** such as typhoid and enteritis caused by *Salmonella species.*

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

POSSIBLE ADVERSE EFFECTS: Most of the adverse reactions observed in clinical trials are mild and self-limiting in nature. Some of the common side effects include diarrhea, loose or frequent stools, abdominal pain, nausea, dyspepsia, flatulence, headache, dizziness, anaphylactic reactions, skin rashes, urticaria, drug fever, pruritus, transient thrombocytopenia, leukopenia, neutropenia and mild transient changes in liver and renal function tests which cease on discontinuation of therapy.

DRUG INTERACTIONS: *Carbamazepine:* Elevated carbamazepine levels have been reported in post-marketing experience when cefixime is administered concomitantly. *Warfarin & other anticoagulants:* Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

WARNINGS: *Hypersensitivity Reactions:* Before treatment 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 gross hypersensitivity among beta-lactam antibiotic has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. *Pseudomembranous Colitis:* Pseudomembranous colitis has been reported with the use of cefixime and other broad-spectrum antibiotics (including macrolides, semi synthetic penicillins, and cephalosporins); therefore, it is important to consider this diagnosis in patients who develop diarrhea in association with the use of antibiotics. *Renal Impairment:* The dose of cefixime should be adjusted in patients with renal

impairmentas well as those undergoing continuous ambulatory peritoneal dialysis (CAPD) and hemodialysis (HD). Patients on dialysis should be monitored carefully. *General:* Cephalosporins 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. *Use in Pregnancy:* There are no adequate and well-controlled studies in pregnant women; this drug should be used during pregnancy only if clearly needed. *Lactation:* It is not known whether cefixime is excreted in human milk. Consideration should be given to discontinuing nursing temporarily during treatment with this drug. *Pediatric Use:* Safety and effectiveness of cefixime in children aged less than 6 months old have not been established.

DOSAGE & ADMINISTRATION: *Adults:* The recommended dose of Cefiscot is 400 mg once-daily. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of Cefiscot 400 mg is recommended. *Children:* The recommended dose is 8 mg/kg/day of Cefiscot Suspension. This may be administered as a single daily dose or may be given in 2 divided doses, as 4 mg/kg every 12 hours. As a general guide for prescribing in children, the following daily doses in terms of volume of Cefiscot Suspension are suggested:

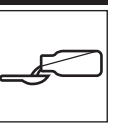
AGE (Years)	DOSAGE	
	Cefiscot Susp.	Cefiscot DS Susp.
1-4	5 ml daily	2.5 ml daily
5-9	10 ml daily	5 ml daily
10-12	15 ml daily	7.5 ml daily
Adults & children above 12 years	-	10 ml daily
Not recommended for children below 6 months of age.		

Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose. Otitis media should be treated with the suspension, as suspension results in higher peak blood levels than the capsule when administered at the same dose. Therefore, the capsule should not be substituted for the suspension in the treatment of otitis media.

METHOD OF PREPARATION

Tap the bottle to loosen the powder. Put some boiled and cooled water into the bottle and shake well.

Add more boiled and cooled water into the bottle upto the mark on the label and shake vigorously.



Suspension is ready for use. Once dispensed the suspension must be used within 7 days.

SPECIAL INSTRUCTIONS TO THE PHYSICIAN: *Renal Impairment:* Normal dose and schedule may be employed in patients with creatinine clearances of 60 mL/min or greater. Patients whose creatinine clearance is between 21 and 60 mL/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval. Patients whose creatinine clearance is <20 mL/min, or patients who are on continuous ambulatory peritoneal dialysis may be given half the standard dosage at the standard dosing interval. *Overdosage:* Gastric lavage may be indicated; otherwise, no specific antidote exists.

STORAGE/PRECAUTIONS: Store in a cool, dry and dark place between 15-30 ºC. Keep all medicines out of the children's reach.

PRESENTATION: Cefiscot Capsules are available in packing containing 5 capsules, whereas Cefiscot Suspension is available in a bottle (approx. 30 & 60 ml, respectively when prepared as directed) & Cefiscot DS Suspension is available in a bottle (approx. 30 ml when prepared as directed). *Scotmann Specs.

عمومی خوراک: ڈاکٹر کی ہدایت کے مطابق۔ احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ روشنی، نمی اور گرمی سے بچائیں۔ 15 سے 30 ڈگری سینٹی گریڈ کے درمیان محفوظ کریں۔ تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Complete Medical Information available only for doctors on request.

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