Nifim

(C e f i x i m e)

نائفم

(سيفيكزائم)

COMPOSITION

Nifim suspension:

Each 5ml of reconstituted suspension contains:
Cefixime trihydrate USP equivalent to Cefixime 100mg

Nifim DS suspension:

Each 5ml of reconstituted suspension contains:
Cefixime trihydrate USP equivalent to Cefixime 200mg

Nifim 400mg Capsule:

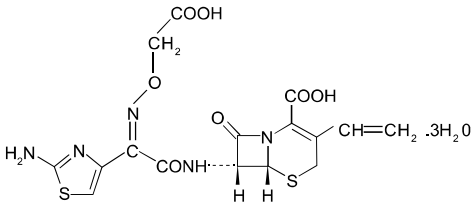
Each capsule contains:
Cefixime trihydrate USP equivalent to cefixime 400mg

DESCRIPTION

Nifim (cefixime) is a semisynthetic, cephalosporin antibiotic for oral administration. Chemically, it is (6R,7R)-7-[2- (2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5- thia-1- azabicyclo[4.2.0] oct-2-ene-2-carboxylic acid, 7^2-(Z)-[O- (carboxymethyl) oxime] trihydrate.

Molecular weight = 507.50 as the trihydrate. Chemical formula is $C_{16}H_{15}N_5O_7S_2.3H_2O$

The structural formula for cefixime is:



CLINICAL PHARMACOLOGY

Pharmacodynamics

Cefixime is an oral third generation cephalosporin which has marked in vitro bactericidal activity against a wide variety of Gram-positive and Gram-negative organisms. Clinical efficacy has been demonstrated in infections caused by commonly occurring pathogens including *Streptococcus pneumoniae, Streptococcus pyogenes, Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenzae* (beta-lactamase positive and negative), *Branhamella catarrhalis* (beta-lactamase positive and negative) and *Enterobacter species*. It is highly stable in the presence of beta-lactamase enzymes.

Most strains of *Enterococci* (*Streptococcus faecalis*, group D *Streptococci*) and *Staphylococci* (including coagulase positive and negative strains and methicillin-resistant strains) are resistant to cefixime. In addition, most strains of *Pseudomonas, Bacteroides fragilis*, *Listeria monocytogenes* and *Clostridia* are resistant to cefixime.

Pharmacokinetics

Only 40 to 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. Absorption is fairly slow; peak plasma concentrations of 2 to 3 micrograms/mL and 3.7 to 4.6 micrograms/mL have been reported between 2 and 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 impairment. About 65% of cefixime is bound to plasma proteins. Information on the distribution of cefixime in body tissues and fluids is limited. It 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 non renal mechanisms; there is no evidence of metabolism but some is probably excreted into the faeces from bile. It is not substantially removed by dialysis.

INDICATIONS

Nifim (Cefixime) is indicated in the treatment of the following infections:

- **Pharyngitis** and **Tonsillitis** caused by. *S.pyogenes*.
- **Otitis Media** caused by *Haemophilus influenza* (beta-lactamase positive and negative strains). *Moraxella*, (*Branhamella*) *catarrhalis*. (most of which are beta-lactamase positive) and *S.pyogenes*.
- **Acute Bronchitis** & **Acute Exacerbations of Chronic Bronchitis** caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* (beta-lactamase positive and negative strains).
- **Typhoid** (Enteric fever caused by *Salmonella typhi*)
- **Uncomplicated Urinary Tract Infections** caused by *Escherichia coli* and *Proteus mirabilis*.
- **Uncomplicated gonorrhea** (cervical/urethral) caused by *Neisseria gonorrhoeae* (penicillinase and non-penicillinase producing strains).

DOSAGE AND ADMINISTRATION

- **Adults:** The recommended dose is 400mg daily. This may be given as a 400mg capsule daily. Duration of treatment should be 7-14 days depending on severity. Uncomplicated cervical/urethral gonococcal infections: a single oral dose of 400mg.
- **Pediatric Patients (6 months or older)**: The recommended dose is 8mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4mg/kg every 12 hours.

Paediatric Dosage Table

Patient Wt. (Kg)	Dose/Day (mg)	Dose/Day
6.25	50	2.5ml Nifim Susp.
12.5	100	5ml Nifim Susp. or 2.5ml Nifim DS Susp.
18.75	150	7.5ml Nifim Susp.
25	200	10ml Nifim Susp. or 5ml Nifim DS Susp.
31.25	250	12.5ml Nifim Susp.
37.5	300	15ml Nifim Susp. or 7.5ml Nifim DS Susp.

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

RENAL IMPAIRMENT

Nifim (Cefixime) may be administered in the presence of impaired renal function. Normal dose and schedule may be employed in patients with creatinine clearances of 60ml/min or greater. Patients whose clearance is between 21 and 60ml/min or patients who are on renal hemodialysis may be given 75% of the standard dosage at the standard dosing interval (ie, 300mg daily). Patients whose clearance 20ml/min may be given half the standard dosage at the standard dosing interval (ie, 200mg daily).

SIDE EFFECTS

The drug is generally well tolerated. The most frequent side effects observed are diarrhea and color changes of stool that has been more commonly associated with higher doses. If severe diarrhea occurs, cefixime should be discontinued. Nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported. Less frequently occuring other side effects are headache & dizziness. Allergies in the form of rash, pruritus, urticaria, drug fever and arthralgia have been reported. These reactions usually subsided upon discontinuation of therapy.

CONTRAINDICATION

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

DRUG INTERACTIONS

Carbamazepine: Elevated carbamazepine levels have been reported when cefixime is administered concomitantly.

Warfarin and Anticoagulants: Increased prothrombin time, with or without clinical bleeding, has been reported when cefixime is administered concomitantly.

PRECAUTION

Cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis. In severe renal failure dosage adjustment is necessary.

PREGNANCY AND LACTATION

No data are available. Cefixime should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

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 small numbers of healthy adult volunteers receiving single doses up to 2g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

STORAGE

Store in a cool (below 25˚C), dry place and away from light. Keep all medicines out of reach of children.

DIRECTIONS FOR RECONSTITUTION OF SUSPENSION

Add one cup of water to the contents in the bottle, invert & shake to make the suspension.
Reconstituted suspension should be consumed within a week.

دوا بنانے کا طریقہ:

سسپنشن بنانے کے لئے دیئے گئے پیمانے میں پانی بھر کر بوتل میں ڈالیں

اور اچھی طرح ہلالیں تا کہ تمام پاؤڈر پانی میں یکساں طور پر حل ہو جائے۔

نوٹ: پانی ملانے کے بعد ۳۰ ملی لیٹر سسپنشن حاصل ہوتا ہے،

جسے ایک ہفتہ تک استعمال کیا جا سکتا ہے۔

PRESENTATION

Nifim Suspension: Each bottle containing fine powder for preparation of 30ml suspension. Each 5ml contains cefixime 100mg.

Nifim DS Suspension: Each bottle containing fine powder for preparation of 30ml suspension. Each 5ml contains cefixime 200mg.

Nifim 400mg Capsule: Alu alu Blister containing 5 capsules. Each capsule contains cefixime 400mg.

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

خشک اور ٹھنڈی جگہ پر روشنی سے بچا کر رکھیں۔

استعمال سے پہلے اچھی طرح ہلالیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
Macquin's
MACQUIN'S INTERNATIONAL
F-2/H, S.I.T.E., Karachi
ISO 9001: 2000 Certified Company

Marketed by:
CENRJY Pharmaceuticals