TORPIZ
[Cefixime]

ٹورپز
کمپوزٹ پاؤڈر اور اول سسپنشن کے لیے۔

DESCRIPTION:
TORPIZ (Cefixime) is a semisynthetic third generation cephalosporin antibiotic.
QUALITATIVE & QUANTITATIVE COMPOSITION:
TORPIZ (Cefixime) is available for administration as:
1.TORPIZ 200mg Capsules
Each capsule contains:
Cefixime as Cefixime Trihydrate..... 200mg
(Product Specs.: JP)
2.TORPIZ 400mg Capsules
Each capsule contains:
Cefixime as Cefixime Trihydrate..... 400mg
(Product Specs.: JP)
3.TORPIZ 100mg/5mL Powder for Oral Suspension
Each 5mL of reconstituted suspension contains:
Cefixime as Cefixime Trihydrate 100mg
(Product Specs.: USP)
4.TORPIZ 200mg/5mL Powder for Oral Suspension
Each 5mL of reconstituted suspension contains:
Cefixime as Cefixime Trihydrate 200mg
(Product Specs.: USP)
CLINICAL PHARMACOLOGY:
Mechanism of Action:
Cefixime exhibits its bactericidal action by binding to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, causing the inhibition of the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins. The antibacterial effect of cefixime results from inhibition of mucopeptide synthesis in the bacterial cell wall.
Microbiology:
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. Spectrum of cefixime is broad and it is active against most strains of the following micro-organisms in both invitro and invivo. Ceftixime has a longer duration of action than other cephalosporins that are active by mouth.
Aerobic Gram-Negative Microorganisms:
Haemophilus influenzae (beta-lactamase positive and negative strains), Moraxella (Branhamella) catarrhalis (most of which are beta-lactamase positive), Escherichia coli, Proteus mirabilis, Neisseria gonorrhoeae (including penicillinase- and nonpenicillinase-producing strains). Klebsiella species.
Aerobic Gram-Positive Microorganisms:
Streptococcus pneumoniae, Streptococcus pyogenes.
Resistant Microorganisms:
Pseudomonas species, strains of group D streptococci (including enterococci), Listeria monocytogenes, most strains of staphylococci (including methicillin-resistant strains), most strains of Enterobacter, most strains of Bacteroides fragilis and Clostridia.
PHARMACOKINETICS:
Absorption & Distribution:
Cefixime given orally, is about 40%-50% absorbed whether administered with or without food, however, time to maximal absorption is increased approximately 0.8 hours when administered with food. Cefixime is better absorbed from oral suspension than from other oral dosage forms. The plasma half life is usually about 3-4 hours. Cefixime is approximately 65% bound to plasma proteins, independent of drug concentration. Cefixime crosses the placenta.
Metabolism & Elimination:
Approximately 50% of an absorbed dose of cefixime is excreted as unchanged drug in the urine in 24 hours. Up to 60% may be eliminated by non-renal mechanism; there is no evidence of metabolism but some is probably excreted into the feces from bile.
Special Populations:
Renal Insufficiency:
In subjects with moderate impairment of renal function (20 to 40mL/min creatinine clearance), the average serum half-life of cefixime is prolonged to 6.4 hours. In severe renal impairment (5 to 20mL/min creatinine clearance), the half-life increased to an average of 11.5 hours. The drug is not cleared significantly from the blood by hemodialysis or peritoneal dialysis.
THERAPEUTIC INDICATIONS:
TORPIZ (Cefixime) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:
- Uncomplicated urinary tract infections.
- Otitis media.
- Pharyngitis and tonsillitis.
- Acute bronchitis and acute exacerbations of chronic bronchitis.
- Uncomplicated gonorrhea (cervical/urethral).

DOSAGE AND ADMINISTRATION:
Adults and Children over 12 Years:
The recommended adult dose of **TORPIZ** (Cefixime) is 200 - 400mg daily according to the severity of infection, given either as a single dose or in two divided doses.
Uncomplicated Cervical/Urethral Gonococcal Infections:
Single oral dose of 400mg is recommended.
Children:
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 except for urinary tract infection where once daily dosing must be used.

Patient Weight (kg)	Dose/Day (mg)	TOPRIZ 100mg/5mL		TOPRIZ 200mg/5mL	
		Dose/Day (mL)	Dose/Day (Tsp of suspension)	Dose/Day (mL)	Dose/Day (Tsp of suspension)
6.25	50	2.5	½	1.25	¼
12.50	100	5	1	2.5	½
18.75	150	7.5	1½	3.75	¾
25	200	10	2	5	1
31.25	250	12.5	2½	6.25	1¼
37.5	300	15	3	7.5	1½
Children weighing more than 50 kg older than 12 years should be treated with the recommended adult dose.					

Otitis Media:
Otitis media should be treated with the suspension.
Duration of Therapy:
The usual course of treatment is 7 days. This may be continued for up to 14 days if required. In the treatment of infections due to S. pyogenes, a therapeutic dosage of **TORPIZ** (Cefixime) should be administered for at least 10 days.
Special Populations:
Renal Impairment:
In patients whose creatinine clearance is less than 20mL/min & patients who are maintained on chronic ambulatory peritoneal dialysis or hemodialysis, a dose of 200mg once daily should not be exceeded.
Directions for Reconstitution:
- Loosen the powder by shaking the bottle.
- Detach the top flat end of plastic ampoule by twisting and add provided sterile water into the bottle.
- Close the cap tightly and shake vigorously.
- Keep tightly close after use.
- Shake well before use.

CONTRAINDICATIONS:
Cefixime is contraindicated in;
- Patients with known allergy to the cephalosporin group of antibiotics.
- Children less than six months old.

PRECAUTIONS:
- Cephalosporins should be given with caution to penicillin sensitive patients, as there is some evidence of partial cross allergenicity between the penicillins and cephalosporins.
- Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Pseudomembranous colitis is associated with the use of broadspectrum antibiotics (including macrolides, semi-synthetic penicillins, lincosamides and cephalosporins); it is therefore important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Symptoms of pseudomembranous colitis may occur during or after antibiotic treatment.
- Broad-spectrum antibiotics such as cefixime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Do not use cefixime to treat S. aureus as this strain of staphylococci is resistant to cefixime.

Pregnancy:
Cefixime should not be used in pregnancy unless considered essential by the physician.
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 INTERACTIONS:
Anticoagulants:
Care should be exercised in patients receiving anticoagulants and cefixime concomitantly due to the possibility that cefixime may increase prothrombin time.
Carbamazepine:
Elevated carbamazepine levels have been reported, when cefexime is administered concomitantly. Carbamazepine levels should be monitor.
Drug/Laboratory Interactions:
- A false-positive reaction for ketones in the urine may occur with tests using nitroprusside.
- A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.
- A false-positive direct Coombs test has been reported during treatment with cephalosporin antibiotics, therefore it should be recognized that a positive Coombs test may be due to the drug.

ADVERSE REACTIONS:
Cefixime is generally well tolerated and side effects are usually transient.
Gastrointestinal Disturbance:
Diarrhea (if severe diarrhea occurs, cefixime should be discontinued), changes in the color of stool, nausea, abdominal pain, dyspepsia, vomiting, flatulence have been reported. Pseudomembranous colitis has also been reported.
Central Nervous System Disturbance:
Headache, dizziness, seizures.
Hepatic Disorders:
Transient rises in liver enzymes and jaundice can also occur.
Others:
Hypersensitivity reactions, infrequent and reversible hematological changes, elevation of serum amylase. Increase in prothrombin time. Other possible reactions include genital pruritis and vaginitis.
OVERDOSAGE:
Gastric lavage may be indicated in overdosage. No specific antidote exists. Treatment should be symptomatic. Cefixime is not removed from the circulation in significant quantities by dialysis.
INSTRUCTIONS:
- Store below 30°C.
- Protect from light and moisture.
- The reconstituted can be used for up to 7 days, when stored at room temperature and up to 14 days when refrigerated. Discard unused portion after 14 days.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
TORPIZ 200mg Capsules are available in pack of 5's.
TORPIZ 400mg Capsules are available in pack of 5's.
TORPIZ 100mg/5mL Powder for Oral Suspension is available in pack of 1 Bottle of Powder (30mL) plus 1 ampoule of sterile water (20mL).
TORPIZ 200mg/5mL Powder for Oral Suspension is available in pack of 1 Bottle of Powder (30mL) plus 1 ampoule of sterile water (20mL).

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

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