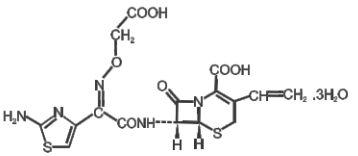
CB-Get
(Cefixime U.S.P)

سی بی ۔گٹ
(سیفیکزائم یو ایس پی)

400mg Capsules
100mg/5mL Powder for Oral Suspension
200mg/5mL DS Powder for Oral Suspension

DESCRIPTION
CB GET (Cefixime) is a semisynthetic third generation cephalosporin antibiotic. Chemically cefixime is a described as (6R,7R)-7-(12-(2-Amino-4-thizolyl)glyoxylamido)-8-oxo-3-vinyl-5-thia-1-azabicyclo(4.2.0)oct-2-ene carboxylic acid, 7²-(Z)-(O-(carboxymethyl(Oxime) trihydrate.
The molecular formula is $C_{16}H_{15}N_5O_7S_2.3H_2O$ and the structural formula is:



Cefixime Trihydrate

QUALITATIVE & QUANTITATIVE COMPOSITION
CB-GET (Cefixime) is a available for oral administration as:

1. CB-GET Capsules 400mg
   Each capsule contains:
   Cefixime trihydrate equivalent to Cefixime 400mg

2. CB-GET Dry Powder for Oral Suspention 100mg/5ml
   Each 5ml of reconstituted suspension contains:
   Cefixime trihydrate equivalent to Cefixime USP 100mg

3. CB-GET Dry-Poweder for Oral Suspension 200mg/5mL
   Each 5mL of reconstituted suspension contains:
   Cefixime trihydrate equivalent to Cefixime USP 200mg

CLINICAL PHARMACOLOGY
Mechanism of Action
Cefixime has marked in vitro bacteriocidal activity of gram positive and gram negative. Like other cephalosporins, cefixime exhibits its bacteriocidal 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 cefixim e results from inhibition of mucopeptide synthesis in the bacterial cell wall.

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 & Excretion
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 hemodialys is or peritoneal dialysis.

Microbiology
Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result many organisms resistant to penicillin and some cephalosporins due to the presence of beta-lactamasesmay be susceptible to cefixime. Spectrum of cefixime is broad and it is active against most strong of the following micro-organisms in both invitro and invivo. Cefixime has a longer duration of action than other cephalosporins that are active by mouth.

Gram-positive Organisms
Streptococcus pneumoniae,
Streptococcus pyogenes.

Gram-negative Organisms
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 non-penicillinase-producing strains).
Klebsiella species.

Note:
Pseudomonas species, strains of group D streptococci(including enterococci), Listeria monocytogenes, most strains of staphylococci (including methicillin-resistant-strains) and most strains of Enterobacter are resistant to cefixime. In addition, moststrains of Bacteroides fragilis and Clostridia are resistant to cefixime.

THERAPEUTIC INDICATIONS
CB-GET (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 10 years:
The recommended adultdose of CB-Get (Cefixime) is 200- 400mg daily according tothe severity of infection, given either as a single dose or in two divided doses.

Uncomplicated cervical/urethral gonococcal infections: For the treatment of uncomplicated cervical/urethral gonococcal infections. a 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 1 2 hours except for urinary tract infection where once daily dosing must be used. As a general guide for prescribing in children the following daily doses in terms of volume of pediatric oral suspension are suggested:
6 months up to 1 year: 3.75mL. daily
Children 1-4 years: 5mL daily
Children 5-10 years: 10ml daily
Children weighing more than 50 kg or older than 10 years should be treated with the recommended adult dose (200-400 mg daily depending on the severity of infection)
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 5 pyogenes, a therapeutic dosage of CB GET (Cefixime) should be administered for at least 10 days.

Special Populations
Renal Insufficiency
CB-GET (Cefixme) may be administered in the presence of impaired renal function. Normal dose and schedule may be given in patients with creatinine clearances of 20ml/min or greater in patients whose creatinine clearance is less than 20ml/min, it is recommended that a dose of 200mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or hemodialys is should follow the same recommendation as that for patients with creatinine clearances of less than 20mL/min.

Directions for Preparing Oral Suspension
Fill previously boiled and cooled water up to the mark on the bottle and shake vigorously.

After reconstitution the suspension maybe kept for 7 days at room temperature, or under refrigeration may be kept for 14 days, without significant loss of potency. Keep tightly closed. Shake well before using. Discard unused portion after 14 days.

ADVERSE REACTIONSC Cefixime is generally well tolerated a 1 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 transaminases, alkaline phosphatase and jaundice can also occur.
Others: Hypersensitivity reactions which usually subside upon discontinuation of therapy; infrequent and reversible hematological changes; elevation of serum amylase. Increase in prothrombin time has been reported in few patients. Other possible reactions include genital pruritis and vaginitis.

CONTRAINDICATIONS
Cefixime is contraindicated in:
- Patients wi th hypersensitivity to any component of this medication.
- Patients with known allergy to the cephalosporin group of antibiotics.
- Children less than six months old as safety and efficacy of cefixime in these patients have not been established.

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.
- Cefixime should be administered with caution in patients with markedly impaired renal function.
- Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia.
Pseudomembranous coitis is associated with the use of broad-spectrum antibiotics (including macrolides, semi-syntheticpenicillins, 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-spec trum an tibiotics 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
There are no adequate and well-controlled studies in pregnant women. Cefixime should therefore 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 cefixme may increase prothrombin time.

Carbamazepine: Elevated carbamazepine levels have been reported, when cefexime is administered concomita ntly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Drug/Laboratory Interactions
- A false-positive re action for ketones in the urine may occur with tests using nitroprusside but not with those using nitroferricyanide.
- A false-positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions.
- 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.

STORAGE
Store below 30°C.
Protect from sunlight and moisture.
The expiration date refers to the product correctly stored at therequired conditions.

HOW SUPPLIED

- CB-GET (Cefixime) Capsules 400mg are available in blister pack of 5 Capsules.

- CB-GET (Cefixime) Powder for Oral Suspension is available in 30ml in 60ml bottles.

- CB-GET DS (Cefixime) Powder for Oral Suspension is available in 30mL in 60ml bottles.

Keep out of reach of children.
To be sold on prescription of a registered medical practitioner only.

سسپنشن تیار کرنے کا طریقہ:
اُبلا ہوا ٹھنڈا پانی ڈبے کے اندر دیئے گئے پیمانہ سے بوتل میں ڈالیں۔
بوتل کو اچھی طرح ہلائیں یہاں تک کہ تمام پاؤڈر پانی میں مل جائے۔

ہدایات:
استعمال سے پہلے بوتل کو اچھی طرح ہلائیں۔
تیار شدہ سسپنشن اگر کمرے کا درجہ حرارت (۱۵ سے ۳۰ ڈگری سینٹی گریڈ) پر رکھا گیا ہو تو ۷ دن تک اور اگر ریفریجریٹر (۲ سے ۸ ڈگری سینٹی گریڈ) پر رکھا گیا ہو تو ۱۴ دن تک استعمال کیا جا سکتا ہے۔
دوا کو روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
استعمال کے بعد بوتل کو اچھی طرح بند کریں۔

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