Orcef®

(Cefixime tablet, capsule and oral suspension)
For oral use only

Presentation
Orcef® 200mg Tablet: Each film coated tablet contains 200mg cefixime as Cefixime trihydrate USP .
Orcef® 400mg Tablet: Each film coated tablet contains 400mg cefixime as Cefixime trihydrate USP .
Orcef® 200mg Capsule: Each capsule contains 200mg cefixime as Cefixime trihydrate USP.
Orcef® 400mg Capsule: Each capsule contains 400mg cefixime as Cefixime trihydrate USP.
Orcef® Dry powder for suspension: Each 5 ml of reconstituted suspension contains 100mg cefixime as Cefixime trihydrate USP.
Orcef®DS Dry powder for suspension: Each 5 ml of reconstituted suspension contains 200mg cefixime as Cefixime trihydrate USP.

Microbiology
Orcef® (Cefixime) is a broad spectrum cephalosporin antibiotic of third generation for oral administration. As with other cephalosporins, bactericidal action of Cefixime results from inhibition of bacterial 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. Cefixime has been shown to be active against most strains of the following organisms both in vitro and in clinical infections

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).
Cefixime has been shown to be active in vitro against most strains of the following organisms; however, clinical efficacy has not been established.

Gram-positive Organisms: *Streptococcus agalactiae*.

Gram-negative Organisms: *Haemophilus parainfluenzae* (beta-lactamase positive and negative strains), *Proteus vulgaris, Klebsiella pneumoniae, Klebsiella oxytoca, Pasteurella multocida, Providencia species, Salmonella species, Shigella species, Citrobacter amalonaticus, Citrobacter diversus, Serratia marcescens.*

Indications and usage
Orcef® (Cefixime) is indicated in the treatment of the 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 (Branhamella) catarrhalis.* (most of which are beta-lactamase positive) and *S.pyogenes*.
- **Pharyngitis and Tonsillitis** caused by. *S.pyogenes.*
- **Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis** caused by *Streptococcus pneumoniae and Haemophilus influenzae* (beta-lactamase positive and negative strains).
- **Uncomplicated gonorrhea (cervical/urethral)** caused by *Neisseria gonorrhoeae* (penicillinase and non-penicillinase producing strains).
- **Typhoid** (Enteric fever caused by *Salmonella typhi*)

Dosage and Administration
Adults: The recommended dose is 400mg daily. This may be given as a 400 mg tablet/capsule daily or as 200mg tablet/capsule every 12 hours. Duration of treatment should be 7 - 14 days depending on severity.
Uncomplicated cervical/urethral gonococcal infections: a single oral dose of 400mg.
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.

Pediatric dosage chart

Patient Weight (kg)	Dose/Day (mg)	Dose/Day (ml)	Dose/Day tsp (5ml) of suspension
6.25	50	2.5	½
12.5	100	5.0	1
18.75	150	7.5	1½
25.0	200	10.0	2
31.25	250	12.5	2½
37.5	300	15.0	3

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.

In the treatment of infections due to *S.pyogenes*, a therapeutic dosage of **Orcef®** (Cefixime) should be administered for at least 10 days.

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

Side effects
The drug is generally well tolerated. Most of adverse reactions observed in clinical trials were of a mild and transient nature. The most frequent side effects observed are diarrhea and colour 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
Orcef®(Cefixime) is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

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

Use in 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.

Pediatric Use
Efficacy and safety in children aged less than 6 (six) months have not been established.

Drug Interaction
No data are available

Preparation of Suspension

Reconstituted volume of Orcef dry powder for suspension	Required amount of boiled and cooled water	Reconstitutions process
70ml	35ml	First, shake the bottle to loosen granules. Then add the water in two approximately equal portions, shaking vigorously after each addition of water
50ml	35ml	
40ml	20ml	
30ml	15ml	
50ml DS	30ml	

Note: After reconstitution, the suspension may be kept for 10 days either at room temperature, or under refrigeration, without significant loss of potency. Shake the suspension well before each use. Keep the bottle tightly closed.

Storage
Store in a cool (below 30°C), dry place and away from light. Keep all medicines out of reach of children.

How supplied
Orcef® 200mg F.C. tablet: Each box contains 2 Alu-alu blister of 6 tablets.
Orcef® 400mg F.C. tablet: Each box contains 1 Alu-alu blister of 6 tablets.
Orcef® 200mg capsule: Each box contains 2 Alu-alu blister of 8 capsules.
Orcef® 200mg capsule: Each box contains 1 Alu-alu blister of 8 capsules.
Orcef® 400mg capsule: Each box contains 1 Alu-alu blister of 6 capsules.
Orcef® Oral Suspension provides the equivalent of 100mg Cefixime per 5 ml suspension (when constituted as directed) and is available in 70 ml, 50 ml, 40 ml & 30 ml size.
Orcef®DS Oral Suspension provides the equivalent of 200mg Cefixime per 5 ml suspension (when constituted as directed) and is available in 50 ml size

®Trade Mark

Manufactured by
Renata Limited
Rajendrapur, Gazipur, Bangladesh

Updated: January, 2017
C-Code : 105212637/V01

88 x 268mm

C-Code & Version	: 105212637/V01
Basic Dimension	: 88 x 268 mm
Dimension Details	: ☐ As Indicated Above ■ N.A.
No. of Folding	: ■ 3 Fold ☐ N.A.
Printing Option	: ■ Both Side ☐ One Side
Paper Density	: ■ 55gsm
No. of Color	: 1
	1. C-0 M- 0 Y-0 K-100
Text on White Background	: Black