SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CEFIWEL 400 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Cefixime USP as Trihydrate
Eq. to anhydrous Cefixime 400 mg Colour: Titanium Dioxide USP

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film coated Tablets
White to off white, elongated, biconvex, one side scored & other side plain film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Acute exacerbations of chronic bronchitis Community-acquired Pneumonia Uncomplicated lower urinary tract infections Uncomplicated pyelonephritis In the treatment of:
Otitis media Sinusitis Pharyngitis

4.2 Posology and method of administration

The recommended dose for adults is 400 mg daily taken as a single dose. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.
Elderly patients
Elderly patients may be given-the same dose as recommended for adults. Renal function should be assessed and dosage should be adjusted in severe renal impairment.
Adolescent's ≥ 12 years of age
Adolescent's ≥ 12 years of age may be given the same dose as recommended for adults.
Children from 6 months to 11 years of age
It is recommended that Children from 6 months to 11 years of age be given Cefixime as an oral suspension. The recommended dosage for children is 8 mg / kg body weight/ day administered as a single dose or in two divided doses.
Children less than 6 months of age
The safety and efficacy of Cefixime has not been established in children less than 6 month of age.
Renal insufficiency
Cefixime may be administered in the presence of impaired renal function, Normal dose and schedule may be given in patients with creatinine clearances of 20 ml/min or greater. In patients whose creatinine clearance is less than 20 ml/min, ii is recommended that a dose of 200 mg once daily should not be exceeded. The dose and regimen for patients who are maintained on chronic ambulatory peritoneal dialysis or haemo-dialysis should follow the same recommendation as that for patients with creatinine clearances of less than 20 ml/min.

There are insufficient data regarding use of Cefixime in the paediatric and adolescent age group in the presence of renal insufficiency.
Therefore, the use of Cefixime in these patient-groups is not recommended.

Method of administration
Cefixime tablets are .for oral administration only. Cefixime tablets should be taken with a sufficient amount of water. Cefixime may be taken with or without food.

4.3 Contraindications
Hypersensitivity to Cefixime, other cephalosporin antibiotics. Previous immediate and/or severe hypersensitivity reaction to penicillin or any beta lactam antibiotic.

4.4 Special warnings and precautions for use
Cefixime should be given with caution to patients who have shown hypersensitivity to other drugs. Cephalosporins should be given with caution to penicillin-sensitive patients, as there is some evidence of partial cross-allergen city between the penicillin's and cephalosporins. Patients have had severe reactions (including anaphylaxis) to both classes of drugs.
Special care is indicated in patients who have experienced any allergic reaction to penicillin's or any other beta-lactam antibiotics as cross-reactions may occur. If severe hypersensitivity reactions or anaphylactic reactions occur after administration of Cefixime, the use of Cefixime should be discontinued immediately and appropriate emergency measures should be initiated.

Renal insufficiency
Cefixime should be administered with caution in patients with creatinine clearance < 20 ml/min. There are insufficient data regarding use of Cefixime in the paediatric and adolescent age group in the presence of renal insufficiency. Therefore, the use of Cefixime in these patient-groups is not recommended.
Renal function is to be monitored under a combination therapy with Cefixime preparations and aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics (e.g. furosemide) because of the probability of additional renal impairment. This applies particularly for patients with already restricted renal function. Treatment with Cefixime at the recommended (400mg) dose can significantly alter the normal flora of the colon and lead to overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of antibiotic- associated diarrhoea.
In patients who develop severe persistent diarrhoea during or after use of Cefixime, the risk of life threatening pseudomembranous colitis should be taken into account. The use of Cefixime should be discontinued and appropriate treatment measures should be established.

Management of pseudomembranous colitis should include sigmoidoscopy, appropriate bacteriologic studies, fluids, electrolytes and protein supplementation. If the colitis does not improve after the drug has been discontinued, or if the symptoms are severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by C.difficile. Other causes of colitis should be excluded. The use · of medicinal products inhibiting the intestinal peristalsis is contraindicated.
Influence on laboratory diagnostic tests: 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 recognised that a positive Coombs' test may be due to the drug.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant intake with potentially nephrotoxic substances (such as aminoglycoside antibiotics, colistin, polymyxin and viomycin) and strong-acting diuretics (e.g. ethacrynic acid or furosemide) induce an increased risk of impairment of renal function. Nifedipine, a calcium channel blocker, may increase bio-availability of Cefixime up to 70 %. In common with other cephalosporins, increases in prothrombin time have been noted in a few patients. Care should therefore be taken in patients receiving anticoagulation therapy.

Administration of Cefixime may reduce the efficacy of oral contraceptives. It is therefore recommended to take supple-mental non-hormonal contraceptive measures.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no adequate data from the use of Cefixime in pregnant women. Animal studies do not indicate direct or indirect .harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Cefixime should not be used in pregnant mothers unless considered essential by the physician.

Lactation

It is unknown whether Cefixime is excreted in human breast milk. Animal studies have shown excretion of Cefixime in breast milk. A decision on whether to continue/discontinue breast- feeding or to continue/discontinue therapy with Cefixime should be made taking into account the benefit of breast-feeding to the child and the benefit of Cefixime therapy to the woman. However, until further clinical experience is available, Cefixime should not be prescribed to breast-feeding mothers.

4.7 Effects on ability to drive and use machine

Cefixime has no known influence on the ability to drive and use machines. However, side effects may occur, which may influence the ability to drive and use machines.

4.8 Undesirable effects

Eosinophilia, Hypereosinophilia, Agranulocytosis, Leucopenia, Neutropenia, Granulocytopenia, Haemolytic anaemia, Thrombocytoperiia, Thrombocytosis, Abdominal pain, Diarrhoea, Dyspepsia, Nausea, vomiting, Flatulance; Jaundice, Dizziness, Headache, Dyspnoea, Anaphylactlc reaction, Pruritus, Rash, Drug Fever, Arthralgia, Stevens-Johnson syndrome, Angiooedema, Urticaria, Pyrexia, face oedema.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

There is no experience with overdoses with Cefixime.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Cefixime is an antibacterial agent of the cephalosporin class. Like other cephalosporin's, Cefixime exerts antibacterial activity by binding to and inhibiting the action of penicillin binding proteins involved in the synthesis of bacterial cell walls. This leads to bacterial cell lysis and cell death.

Pharmacotherapeutic group: Antibiotic

Mechanism of action:

Like all beta-lactam antibiotics Cefixime binds 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; it is possible that Cefixime interferes with an autolysin inhibitor.

5.2 Pharmacokinetic properties

Absorption

The absolute oral bioavailability of Cefixime is in the range of 22-54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard

to meals.

Distribution

Serum protein binding is well characterised for human and animal sera; Cefixime is almost exclusively bound to the albumin fraction, the mean free fraction being approximately 30%. Protein binding of Cefixime is only concentration dependent in human serum at very high concentrations, which are not seen following clinical dosing.

Metabolism and Elimination

The pharmacokinetics of Cefixime in healthy elderly (age> 64 years) and young volunteers (11-35) compared the administration of 400 mg doses once daily for 5 days. Mean Cmax and AUG values were slightly greater in the elderly. Elderly patients may be given the same dose as the general population. Cefixime is predominantly eliminated as unchanged drug in the urine. Glomerular filtration is considered the predominant mechanism. Metabolites of Cefixime have not been isolated from human serum or urine.

5.3 Preclinical safety data

There are no Pre-clinical data of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Filleraa-A, Colloidal silicon dioxide, Microcrystalline Cellulose, Magnesium Stearate, Talc, Sodium starch Glycolate, Hypromellose, Polyethylene Glycol, Titanium Dioxide

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container

10 Tablets packed in Alu Poly Strip.

6.6 Special precaution for disposal
Not Applicable

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE

ADDRESS MAH
UNOSOURCE PHARMA LTD.
Unit: 503-504, 5th floor Hubtown Solaris
N.S. Phadke Marg, Andheri (East) Mumbai – 400

Manufacturing Site
Malik Lifesciences Pvt. Ltd.
(A subsidiary company of Akums Drugs & Pharmaceuticals Ltd.)
Plot No.-16 Vardhman Industrial Estate,
Village- Bahadarpur Saini N.H.-58,
Haridwar, Uttarakhand- 247667, India

8. MARKETING AUTHORIZATION NUMBERS
CTD11241/24345

9. DATE OF FIRST REGISTRATION
01-04-2026

10. DATE OF THE REVISION OF THE TEXT

01-04-2026