Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Cefi-Q 400mg Capsules

2. Qualitative and quantitative composition

Each Capsule Contains: Cefixime ……..400mg (As Cefixime Trihydrate)

The product contains 10mg Lactose crystalline (monohydrate) per capsule

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

A hard gelatin capsule of size '0' with print of 'Maxpan' and '400' on Dark blue color cap and white body, containing light yellow granular powder

4. Clinical particulars

4.1 Therapeutic indications

Cefixime is indicated in the treatment of adults and pediatric patients six months of age or older in the following infections caused by susceptible strains of the designated microorganisms:

Upper Respiratory Tract:

Pharyngitis and tonsillitis caused by S. pyogenes.

Middle Ear:

Otitis media caused by S. pneumoniae, H. influenzae (beta-lactamase positive and negative strains), M. catarrhalis(former B. catarrhalis) (beta- lactamase positive andnegative strains) and S. pyogenes.

Paranasal sinuses:

Sinusitis caused by S. pneumoniae, H. Influenza (beta-lactamase positive and negative strains), and M. Catarrhalis (former B. catarrhalis) (beta- lactamase positive and negativestrains).

Lower Respiratory Tract:

Acute bronchitis caused by S. pneumoniae, M. Catarrhalis (former B. catarrhalis)(beta lactamase positive and negative strains) and H. influenzae (beta-lactamase positive and negative strains).

Urinary Tract:

Acute uncomplicated cystitis and urethritis caused by E. coli, P. mirabilis, and Klebsiella species.

Uncomplicated Gonorrhea:

Uncomplicated gonorrhea (cervical/urethral and rectal) caused by Neisseria gonorrhoeae, including penicillinase (beta-lactamase-positive) and non penicillinase (beta- lactamasenegative) producing strains.
Appropriate cultures should be taken for susceptibility testing before initiating treatment with Cefixime. If warranted, therapy may be instituted before susceptibility results are known; however, once these are obtained, therapy may need to be adjusted.

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susceptibility results are known; however, once these are obtained, therapy may need to be adjusted.

4.2 Posology and method of administration

Adults
Adults and children over 10 years or weighing more than 50kg:

The usual daily dose is 200-400 mg in single or twice daily dosage regimen. The recommended dose of cefixime is 400 mg daily. For the treatment of uncomplicated cervical/urethral gonococcal infections, a single oral dose of 400 mg is recommended. The capsule may be administered without regard to food.
In the treatment of infections due to Streptococcus pyogenes, a therapeutic dosage of cefixime should be administered for at least 10 days.

Pediatric Patients (6 months or older)
The recommended dose is 8 mg/kg/day of the suspension. This may be administered as a single daily dose or may be given in two divided doses, as 4 mg/kg every 12 hours.

PEDIATRIC DOSAGE CHART			
		100 mg/5 mL	200 mg/5 mL
Patient Weight (kg)	**Dose/Day (mg)**	**Dose/Day (mL)**	**Dose/Day (mL)**
5 to 6.2	50	2.5	1.25
6.3 to 12.5	100	5	2.5
6.3 to 12.5	150	7.5	3.75
18.9 to 25	200	10	5
25.1 to 31.3	250	12.5	6.25
31.4 to 37.5	300	15	7.5
37.6 to 43.8	350	17.5	8.75
43.9 to 50	400	20	10

Otitis media should be treated with the chewable tablets or suspension. Clinical trials of otitis media were conducted with the chewable tablets or suspension, and the chewable tablets or suspension results in higher peak blood levels than the chewable tablet when administered at the same dose.

Therefore, the tablet or capsule should not be substituted for the chewable tablets or suspension in the treatment of otitis media.

In the treatment of infections due to Streptococcus pyogenes, a therapeutic dosage of cefixime should be administered for at least 10 days

Renal Impairment
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 6.5 ml of Cefixime for Oral Suspension (200 mg/5 mL) daily or 13 ml of Cefixime for Oral Suspension (100 mg/5 mL) daily. Patients whose clearance is 20 mL/min or less, or patients who are on continuous ambulatory peritoneal dialysis may be given 200 mg daily (i.e. half of the 400 mg tablet). Neither hemodialysis nor peritoneal dialysis removes significant amounts of drug from the body.

Strength	**Bottle size**	**Reconstitution Directions**
100 mg/5 mL and 200 mg/5 mL	100 mL	To reconstitute, suspend with **68 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
100 mg/5 mL and 200 mg/5 mL	75 mL	To reconstitute, suspend with **51 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
100 mg/5 mL and 200 mg/5 mL	50 mL	To reconstitute, suspend with **34 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
200 mg/5 mL	37.5 mL	To reconstitute, suspend with **26 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
200 mg/5 mL	25ml	To reconstitute, suspend with **17 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
500 mg/5 mL	20mL	To reconstitute, suspend with **14 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.
500 mg/5 mL	10mL	To reconstitute, suspend with **8 mL water**. Method: Tap the bottle several times to loosen powder contents prior to reconstitution. Add approximately half the total amount of water for reconstitution and shake well. Add the remainder of water and shake well.

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

Method of administration

For oral administration.

The capsules must be swallowed whole, without chewing and accompanied by a little liquid. Cefi-Qcan be taken with or without food

4.3 Contraindications

Cefixime is contraindicated in patients with known allergies to the cephalosporin or any other cephalosporin antibiotic or a known immediate and severe hypersensitivity reaction to penicillin or any beta-lactam antibiotic or to any ingredients in the formulation or component of.

4.4 Special warnings and precautions for use

Hypersensitivity Reactions
Anaphylactic/anaphylactoid reactions (including shock and fatalities) have been reported with the use of cefixime.

Before therapy is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibacterial drugs has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy.

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.

***Clostridium difficile*-Associated Diarrhea/pseudomembranous colitis**
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Cefixime, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing isolates of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

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.

Renal insufficiency

Cefixime should be administered with caution in patients with creatinine clearance < 20ml / min. There are insufficient data regarding use of cefixime in the pediatric 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 impaired renal function and those on haemodialysis.

Coagulation Effects

Cephalosporins, including Cefixime, may be associated with a fall in prothrombin activity. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antimicrobial therapy, and patients previously stabilized on anticoagulant therapy. Prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated

Development of Drug-Resistant Bacteria

Prescribing Cefixime in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Risk in Patients with Phenylketonuria

Phenylalanine can be harmful to patients with phenylketonuria (PKU). Cefixime chewable tablets contain aspartame, a source of phenylalanine. Each 100 mg, 150 mg and 200 mg strength contains 3.3 mg, 5 mg and 6.7 mg of phenylalanine, respectively. Before prescribing Cefixime chewable tablets in a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including the chewable tablets.

The use of medicinal products inhibiting the intestinal peristalsis is contraindicated.

4.5 Interaction 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 bioavailability of cefixime up to70%.

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 such as warfarin and other anticoagulants.

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

Elevated carbamazepine levels have been reported in postmarketing experience when cefixime is administered concomitantly. Drug monitoring may be of assistance in detecting alterations in carbamazepine plasma concentrations.

Drug/Laboratory Test Interactions:

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside but not with those using nitroferricyanide.

The administration of cefixime may result in a false-positive reaction for glucose in the urine using Clinitest®**, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix®** or TesTape®**) be used. A false-positive direct Coombs test has been reported during treatment with other cephalosporins; therefore, it should be recognized that a positive Coombs test may be due to the drug.

4.6 Fertility, pregnancy, and lactation

Pregnancy
Pregnancy Category B

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 (see section 5.3).

Cefixime should not be used in pregnant mothers unless considered essential by the physician. The risk/benefit of administration of Cefixime should be highly critically considered, in particular during the first 3 months of pregnancy.

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 or they should use a breast pump for the duration of therapy and dispose of the milk.

Fertility

Reproduction studies performed in mice and rats have revealed no evidence of impaired fertility.

4.7 Effects on ability to drive and use machines.

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

4.8 Undesirable effects

Very common (≥ 1/10) Common (≥ 1/100 to 1/10)
Uncommon Rare (≥ 1/1,000 to <1/100) Rare (≥ 1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

System Organ Class	**Common ≥1/100 to <1/10**	**Uncommon ≥1/1,000 to <1/100**	**Rare ≥1/10,000 to <1/1,000**	**Very rare <1/10,000**	**Not known (cannot be estimated from the available data)**
Infections and infestations			Prolonged or repeated use may lead to secondary superinfections caused by insusceptible bacteria or fungi.		
Blood and lymphatic system disorders			Eosinophilia	Alteration in blood picture like for example leukopenia, agranulocytosis, pancytopenia or thrombocytopenia. Blood clotting impairment, hemolytic anemia.	Granulocytopenia

Immune system disorders 1			Hypersensitivity reactionsin all degrees, – such as flush, palpitations, dyspnea, drop in blood pressure, bronchospasm, angioneurotic oedema. Severe acute hypersensitivity reactions may manifest as: Facial oedema, swollen tongue, swellingof the inner larynx with restriction of airway, racing heart, shortness of breath (respiratory distress), and decrease ofblood pressure leading to life threatening shock. Any of these occurrences requires immediate medical treatment.	Anaphylactic shock, Reactions similar to serum disease such as arthralgia, arthritis, joint swelling, myalgia, urticaria	

Nervous system disorders 2		Headache	Dizziness	Transient hyperactivity	Convulsions
Gastrointestinaldisorders	Soft stools and diarrhea	Disorders in theform of stomach ache, digestive impairment, nausea, vomiting	Lack of appetite, flatulence	Cases of pseudomembranouscolitis	
Hepatobiliarydisorders		A reversible increase in liverenzymes (transaminase, alkaline phosphatase) inserum		Hepatitis and cholestatic jaundice	Increase of bilirubin
Skin and subcutaneous tissue disorders		Skin rashes (erythema, exanthema)	Pruritus and inflammation of themucous membranes	Erythema exsudativum multiforme, Lyell syndrome and Stevens-Johnson syndrom3	DRESS syndrome
Renal and urinary disorders			Transient increase in urea concentrations in serum have been	Increase in creatinine concentrations in serum, interstitial nephritis	Acute renal failure including tubulointestinal nephritis
General disorders and administrationsite conditions			Mucosal inflammation, pyrexia Drug fever		

Severe acute hypersensitivity reactions may manifest as:

- Facial oedema, swollen tongue, swelling of the inner larynx with restriction of airway, racing heart, shortness of breath (respiratory distress), decrease of blood pressure leading to life- threatening shock. Any of these occurrences requires immediate medical treatment.
- As with other cephalosporins, a raised tendency to convulsive attacks cannot be ruled out.
- Lyell syndrome and Stevens-Johnson syndrome may result in life-threatening conditions.

4.9 Overdose

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 2 g of cefixime did not differ from the profile seen in patients treated at the recommended doses.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: third generation cephalosporin**,** ATC code: J01DD08 Mode of Action
Cefixime is an antibacterial agent of the cephalosporin class. Like other cephalosporins, cefixime exerts antibacterial activity by binding to and inhibiting the action of penicillinbindin proteins involved in the synthesis of bacterial cell walls. This leads to bacterial cell lysis and cell death.

PK/PD relationship
The time that the plasma concentration of cefixime exceeds the MIC of the infecting organism has been shown to best correlate with efficacy in PK/PD studies.

Mechanisms of resistance
Bacterial resistance to cefixime may be due to one or more of the following mechanisms:

• Hydrolysis by extended-spectrum beta-lactamases and / or by chromosomally- encoded (AmpC) enzymes that may be induced or de-repressed in certain aerobic gramnegative bacterial species

• Reduced affinity of penicillin-binding proteins
• Reduced permeability of the outer membrane of certain gram-negative organisms restricting access to penicillin-binding proteins

Drug efflux pumpsBreakpoints
Clinical minimum inhibitory concentration (MIC) breakpoints established by EUCAST

(May 2009) for cefixime are:
□ H. influenzae: sensitive ≤0.12 mg/L, resistant > 0.12 mg/L
□ M. catarrhalis: sensitive ≤0.5 mg/L, resistant > 1.0 mg/L
□ Neisseria gonorrhoeae: sensitive ≤0.12 mg/L, resistant > 0.12 mg/L
□ Enterobacteriaceae: sensitive ≤1.0 mg/L, resistant > 1.0 mg/L (for uncomplicated urinary tract infections only). The breakpoints for Enterobacteriaceae will detect reduced susceptibility mediated by most clinically important beta-lactamases in Enterobacteriaceae

□ Occasional ESBL-producing strains will be reported susceptible. For purposes of infection control, epidemiology and surveillance, laboratories may wish to use specifictests to screen for and confirm ESBL-production.

□ Non-species related breakpoints: insufficient data.

Susceptibility

The prevalence of resistance may vary geographically and over time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

Cefixime has been shown to be active against most isolates of the following bacteria both in vitro and in clinical infections:

Gram-positive bacteria;Streptococcus pneumoniae and Streptococcus pyogenes

Gram-negative bacteria; Haemophilus influenzae, Moraxella catarrhalis Escherichia coli,Proteus mirabilis, Neisseria gonorrhoeae

Cefixime has poor activity against staphylococci (regardless of susceptibility to methicillin)

$ Natural intermediate susceptibility.
% Extended spectrum beta-lactamase (ESBL) producing strains are always resistant. & Resistance rate <10% in isolates of female patients with uncomplicated cystitis, otherwise ≥10%.

5.2 Pharmacokinetic properties

Absorption

The absolute oral bioavailability of cefixime is in the range of 40-50%. whether administered with or without food; however, time to maximal absorption is increased approximately 0.8 hours when administered with food.

A single 200 mg tablet of cefixime produces an average peak serum concentration of approximately 2 mcg/mL (range 1 to 4 mcg/mL); a single 400 mg tablet produces an average peak concentration of approximately 3.7 mcg/mL (range 1.3 to 7.7 mcg/mL). The oral suspension produces average peak concentrations approximately 25% to 50% higher than the tablets, when tested in normal *adult*

volunteers. Two hundred and 400 mg doses of oral suspension produce average peak concentrations of 3 mcg/mL (range 1 to 4.5 mcg/mL) and 4.6 mcg/mL (range 1.9 to 7.7 mcg/mL), respectively, when tested in normal *adult* volunteers. The area under the time versus concentration curve (AUC) is greater by approximately 10% to 25% with the oral suspension than with the tablet after doses of 100 to 400 mg, when tested in normal *adult* volunteers. This increased absorption should be taken into consideration if the oral suspension is to be substituted for the tablet. Because of the lack of bioequivalence, tablets should not be substituted for oral suspension in the treatment of otitis media *[see Dosage and Administration (2)]*. Cross-over studies of tablet versus suspension have not been performed in children.

The 400 mg capsule is bioequivalent to the 400 mg tablet under fasting conditions. However, food reduces the absorption following administration of the capsule by approximately 15% based on AUC and 25% based on C_{max}.

Peak serum concentrations occur between 2 and 6 hours following oral administration of a single 200 mg tablet, a single 400 mg tablet or 400 mg of cefixime suspension. Peak serum concentrations occur between 2 and 5 hours following a single administration of 200 mg of suspension. Peak serum concentrations occur between 3 and 8 hours following oral administration of a single 400 mg capsule.

Distribution

Serum protein binding is well characterised for human and animal sera; cefixime is almost exclusively bound to the albumin fraction, with a bound fraction of approximately 65% and 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. From in vitro studies, serum or urine concentrations of 1 mg/L or greater were considered to be adequate for most common pathogens against which cefixime is active. Typically, the peak serum levels following the recommended adult or paediatric doses are between 1.5 and 3 mg/L. Little or no accumulation of cefixime occurs following multiple dosing.

Adequate data on CSF levels of cefixime are not available.

Metabolism and Elimination

There is no evidence of metabolism of cefixime *in vivo.*

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 AUC values were slightly

greater in the elderly. Elderly patients may be given the same dose as the general population.

Approximately 50% of Cefixime is 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. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose.

Transfer of 14C-labelled cefixime from lactating rats to their nursing offspring through breast milk was quantitatively small (approximately 1.5% of the mothers' body content of cefixime in the pup). No data are available on secretion of cefixime in human breast milk. Placental transfer of cefixime was small in pregnant rats dosed with labeled cefixime.

5.3 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility
Lifetime studies in animals to evaluate carcinogenic potential have not been conducted. Cefixime did not cause point mutations in bacteria or mammalian cells, DNA damage, or chromosome damage *in vitro* and did not exhibit clastogenic potential *in vivo* in the mouse micronucleus test. In rats, fertility and reproductive performance were not affected by cefixime at doses up to 25 times the adult therapeutic dose.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose crystalline (monohydrate)
Microcrystalline cellulose-101
Purified Talc
Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years.

6.4 Special precautions for storage:

Store below 30 °C, protected from moisture and light.

6.5 Nature and contents of container

Each printed box of Cefi-Q 400mg Capsules contains ALU/PVC blister strips of 5 Capsule (1x 5's Capsules) along with the package Inserts

6.6 Special precautions for disposal and other handling:
Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. Marketing authorization holder and manufacturing site addresses
Marketing authorization holder:
Indus Pharma (Pvt) Ltd, 65/27, Korangi Industrial Area, Karachi – 74900, Pakistan
Manufacturing site address:
Indus Pharma (Pvt) Ltd, 65/27, Korangi Industrial Area, Karachi – 74900, Pakistan

8. Marketing authorization number
CTD9899

9. Date of first registration
14/02/2023

10. Date of revision of the text:
13/09/2023

11. Dosimetry:
Not Applicable

12. Instructions for Preparation of Radiopharmaceuticals:
Not Applicable