Summary of Product Characteristics

1. Name of the medicinal product:

CLOFORT 375mg/5ml

(Invented) name of the medicinal product:

Generic Name/INN Name: Cefaclor for Oral Suspension USP 375 mg/5 ml

2. Qualitative and Quantitative composition:

Strength:

Each 5 ml of reconstituted suspension
contains: Cefaclor USP e.q. to:
Anhydrous Cefaclor 375 mg:
Excipients: q.s
For full list of excipients see section 6.1

3. Pharmaceutical form:

Dosage Form: Powder for oral suspension

Strength:

Each 5 ml of reconstituted suspension
contains: Cefaclor USP e.q. to:
Anhydrous Cefaclor 375 mg:
Excipients: q.s

Visual & Physical characteristics of the product:
A white to off-white coloured free flowing powder filled in HDPE bottle which after reconstitution gives pink colored suspension.

4.0 Clinical particulars

4.1 Therapeutic indications:

Cefaclor is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms: Otitis media caused by Streptococcus pneumoniae, Haemophilus influenzae, staphylococci, and Streptococcus pyogenes.
Note: β-lactamase-negative, ampicillin-resistant (BLNAR) strains of Haemophilus influenzae should be considered resistant to cefaclor despite apparent in vitro susceptibility of some BLNAR strains.
Lower respiratory tract infections, including pneumonia, caused by Streptococcus pneumoniae, Haemophilus influenzae, and Streptococcus pyogenes.
Note: β-lactamase-negative, ampicillin-resistant (BLNAR) strains of Haemophilus influenzae should be considered resistant to cefaclor despite apparent in vitro susceptibility of some BLNAR strains.
Pharyngitis and Tonsillitis, caused by Streptococcus pyogenes
Note: Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefaclor is

generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefaclor in the subsequent prevention of rheumatic fever are not available at present.
Urinary tract infections, including pyelonephritis and cystitis, caused by Escherichia coli, Proteus mirabilis, Klebsiella spp., and coagulase-negative staphylococci.
Skin and skin structure infections caused by Staphylococcus aureus and Streptococcus pyogenes. Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to cefaclor.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cefaclor for Oral Suspension and other antibacterial drugs, Cefaclor for Oral Suspension should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

4.2 Posology and method of administration:

Cefaclor is administered orally. Adults -- The usual adult dosage is 250 mg every 8 hours. For more severe infections (such as pneumonia) or those caused by less susceptible organisms, doses may be doubled. Pediatric Patients -- The usual recommended daily dosage for pediatric patients is 20 mg/kg/day in divided doses every 8 hours. In more serious infections, otitis media, and infections caused by less susceptible organisms, 40 mg/kg/day are recommended, with a maximum dosage of 1 g/day.
B.I.D. Treatment Option —For the treatment of otitis media and pharyngitis, the total daily dosage may be divided and administered every 12 hours.

Cefaclor for Oral Suspension USP		
	20 mg/kg/day (Pharyngitis)	
Weight	**187 mg/5 mL**	**375 mg/5 mL**
9 kg	1/2 tsp b.i.d.	
18 kg	1 tsp b.i.d	1/2 tsp b.i.d.
	40 mg/kg/day (Otitis Media)	
9 kg	1 tsp b.i.d	1/2 tsp b.i.d.
18 kg		1 tsp b.i.d

Cefaclor may be administered in the presence of impaired renal function. Under such a condition, the dosage usually is unchanged.
In the treatment of β-hemolytic streptococcal infections, a therapeutic dosage of cefaclor should be administered for at least 10 days.

Directions for Mixing:
Add appropriate water volume as indicated in the following table in two portions to dry mixture in the bottle. Shake well after each addition. Each 5 mL (approximately one teaspoonful) will then contain Cefaclor, USP, monohydrate equivalent to 187 mg or 375 mg anhydrous cefaclor, respectively, as shown in the following table. Oversize bottle provides extra space for shaking.

Cefaclor for Oral Suspension USP

Strength	Water Volume to Add	Anhydrous Cefaclor/5 mL (approx. one teaspoonful)
187 mg/5ml	70 ml	187 mg
375 mg/5 ml	68 ml	375 mg

4.3 Contraindications:
Cefaclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use:
Before therapy with cefaclor is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefaclor, cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among β-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefaclor occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated. Clostridium difficile associated diarrhea (CDAD) has been reported with us e of nearly all antibacterial agents, including Cefaclor for Oral Suspension, USP, and may range in s everity 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. Hypertoxinproducing strains of C. difficile caus e increas ed morbidity and mortality, as thes e infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who pres ent with diarrhea following antibiotic us e. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic us e not directed against C. difficile may need to be dis continued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

Prescribing cefaclor in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increase the risk of the development of drug-resistant bacteria. Prolonged use of cefaclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. It should be recognized that a positive Coombs' test may be due to the drug, e.g., in hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin

antibiotics before parturition.

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Since the half-life of cefaclor in anuria is 2.3 to 2.8 hours, dosage adjustments for patients with moderate or severe renal impairment are usually not required. Clinical experience with cefaclor under such conditions is limited; therefore, careful clinical observation and laboratory studies should be made.

As with other β-lactam antibiotics, the renal excretion of cefaclor is inhibited by probenecid. Antibiotics, including cephalosporins, should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

4.5 Interaction with other medicinal products and other forms of interaction: Antacids

The extent of absorption of cefaclor is diminished if magnesium or aluminium hydroxide- containing antacids are taken within 1 hour of administration; H2 blockers do not alter either the rate or the extent of absorption of cefaclor.

Probenecid

The renal excretion of cefaclor is inhibited by probenecid leading to increased plasma cephalosporin concentrations.

Warfarin

There have been rare reports of increased prothrombin time, with or without clinical bleeding, in patients receiving cefaclor and warfarin concomitantly.

No specific studies have been performed to rule in or rule out this potential drug/drug interaction. It is recommended that in such patients, regular monitoring of prothrombin time should be considered, with adjustment of dosage if necessary. Cefaclor may decrease the efficacy of estrogen-containing oral contraceptives.

4.6 Pregnancy and lactation:

Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given 3 times the maximum human dose and have revealed no harm to the fetus due to cefaclor. There are, however, no adequate and wellcontrolled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

The effect of cefaclor on labor and delivery is unknown.

Nursing Mothers

Small amounts of cefaclor have been detected in mother's milk following administration of single 500- mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/mL at 2, 3, 4, and 5 hours, respectively. Trace amounts were detected at 1 hour. The effect on nursing infants is not known. Caution should be exercised when cefaclor is administered to a nursing woman.

4.7 Effects on ability to drive and use machines:

No effect has been reported.

4.8 Undesirable effects:

In one paediatric study cefaclor was associated with 53.3% of oral antibiotic related skin and joint adverse reactions and 84.1%
of serum sickness like reactions.
Very common (=1/10); 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 form the
available data). Infections and infestations
Frequency not known: Genital pruritus, vaginitis and
vaginal moniliasis. Blood and lymphatic system disorders
Rare: thrombocytopenia, transient lymphocytosis, leucopenia. Other haematological reactions include haemolytic anaemia,
aplastic anaemia, agranulocytosis and reversible neutropenia of possible clinical significance. Frequency not known: Eosinophilia, lymphadenopathy.
Immune system disorders:
Rare: Allergic reactions such as morbilliform eruptions, pruritus and urticaria have been observed. These reactions usually
subside upon discontinuation of therapy. Rarely, hypersensitivity symptoms may persist for several months. Frequency not
known: Serum sickness-like reactions (erythema multiforme minor, rashes or other skin manifestations accompanied by
arthritis/arthralgia, with or without fever) have been reported.
Anaphylactoid events may present as solitary symptoms, including angioedema, asthenia, oedema (including face and limbs),
dyspnoea, paraesthesias, syncope, or vasodilation.
Serum sickness-like reactions are apparently due to hypersensitivity and have usually occurred during or following a second (or
subsequent) course of therapy with cefaclor. Such reactions have been reported more frequently in children than in adults.

Signs and symptoms usually occur a few days after initiation of therapy and usually subside within a few days of cessation of
therapy. Antihistamines and corticosteroids appear to enhance resolution of the syndrome. No serious sequelae have been
reported.

Psychiatric disorders:

Frequency not known: Reversible hyperactivity nervousness, insomnia, confusion, hypertonia, hallucinations.

Nervous system disorders:

Common: Headache
Frequency not known: agitation, dizziness, drowsiness and somnolence

Gastrointestinal disorders:

Common: diarrhoea, colitisnausea and
vomiting. Rare: pseudomembranous
colitis.

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

4.9 Overdose:

Signs and Symptoms -- The toxic symptoms following an overdose of cefaclor may include nausea, vomiting, epigastric distress, and diarrhea. The severity of the epigastric distress and the diarrhea are dose-related. If other symptoms are present, it is probable that they are secondary to an underlying disease state, an allergic reaction, or the effects of other intoxication. Treatment -- To obtain up-to-date information about the treatment of overdose, a good resource is your certified Regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the Physicians' Desk Reference (PDR). In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient. Unless 5 times the normal dose of cefaclor has been ingested, gastrointestinal decontamination will not be necessary. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal. Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cefaclor.

5.0 Pharmacological properties:

Mechanism of Action

As with other cephalosporins, the bactericidal action of cefaclor results from inhibition of cell- wall synthesis.

Mechanism of Resistance

Resistance to cefaclor is primarily through hydrolysis of beta-lactamases, alteration of penicillinbinding proteins (PBPs) and decreased permeability. Pseudomonas spp., Acinetobacter calcoaceticus and most strains of Enterococci (Enterococcus faecalis, group D streptococci), Enterobacter spp., indolepositive Proteus, Morganella morganii (formerly Proteus morganii), Providencia rettgeri (formerly Proteus rettgeri), and Serratia spp. are resistant to cefaclor. Cefaclor is inactive against methicillinresistant staphylococci. β-lactamase-negative, ampicillin-resistant strains of H. influenzae should be considered resistant to cefaclor despite apparent in vitro susceptibility to this agent.

5.1 Pharmacodynamic properties:

ATC-code: J01DC04 Second generation cephalosporins

Cefaclor is a semi-synthetic second generation cephalosporin antibiotic.

Cefaclor is a broad-spectrum, second generation cephalosporin. It is bactericidal

against a wide range of Gram-positive and Gram-negative microorganisms. The reported mode of action is predominantly by the inhibition of cell wall synthesis in susceptible bacteria. This is mainly achieved by inhibiting the trans-peptidation reaction, the final stage of the cell wall synthesis process, thus preventing the complete formation of peptidoglycan cross-links. Other earlier stages in this synthesis process may also be inhibited and there may be some induction of bacterial lysis.

Cefaclor is active against the following organisms in vitro:
Alpha-and beta- haemolytic streptococci
Staphylococci; including coagulase-positive, coagulase-negative and penicillinase-producting strains.
Streptococcus penumoniae
Streptococcus pyogenes (group A beta-haemolytic
streptococci) Moraxella catarrhalis
Escherichia
coli Proteus
mirabilis
Klebsiella
species
Haemophilus influenza, including ampicillin-resistant strains
Cefaclor has no activity against Pseudomonas species or Acinetobaster species. Methicillin- resistant staphylococci and most
strains of Enterobacter spp, Serratia spp, Morganella morganii, Proeus vulgaris and Providencia rettgeri.

5.2 Pharmacokinetic properties:

Cefaclor is well absorbed after oral administration to fasting subjects. Total absorption is the same whether the drug is given with or without food. when it is taken with food, the peak concentration achieved is 50% to 75% of that observed when the drug is administered to fasting subjects and generally appears from ¾ to one hour later. Following administration of 250 mg, 500 mg and 1 g doses to fasting subjects, average peak serum levels of approximately 7, 13 and 23 mg/l, respectively, were obtained within 30 to 60 minutes.

Approximately 60% to 85% of the drug is excreted unchanged in the urine within eight hours, the greater portion being excreted within the first two hours. During the eight hour period, peak urine concentrations following the 250 mg, 500 mg and 1 g doses were approximately 600, 900 and 1900 mg/l respectively. The serum half-life in normal subjects is 0.6 to 0.9 hours.
In patients with reduced renal function, the serum half-life of cefaclor is slightly prolonged. In those with complete absence of renal function, the plasma half-life of the intact molecules is 2.3 to 2.8 hours. Excretion pathways in patients with markedly impaired renal function have not been determined. Haemodialysis shortens the half-life by 25% to 30%.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional

to that already included in other sections of the SPC.

6.0 Pharmaceutical particulars:

6.1 List of Excipients:

Lactose Monohydrate BP
Xanthan Gum BP
Microcrystalline Cellulose and Carmellose sodium
BP Sodium Citrate BP
Citric acid BP
Sodium Benzoate
BP
Neomalt A 200X In-house
Colloidal anhydrous silica
BP
Strawberry Flavour STR DM No. 01 In-
house Colour Ponceau 4R Supra In-
house

6.2 Incompatibilities:

Not applicable.

6.3 **Shelf life:** 36 months

6.4 Special precautions for storage:

Store below 30˚C and in a dry place. Keep the container tightly closed. Protect from light. Once reconstituted the suspension must be used within 7days, if stored at room temperature. Use within 14 days if stored in a refrigerator, shake the bottle before use.

6.5 Nature and contents of container:

Primary Packing: 70 ml clear HDPE bottle.
Secondary Packing: 1 x 70 ml clear HDPE Bottle with child lock cap with 10ml measuring cup.

6.6 Special precautions for disposal:

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder:

Sisi Pharmaceuticals Ltd
Registration certificate no.
CPR/2014/139869 Suite no. 3, Mayfair
Business Centre
Msapo close, off Parklands road
P.O Box 2049-00200
Nairobi

8. Marketing Authorisation number
CTD11774

9. Date of first Authorisation/Renewal of the Authorisation:
03/02/2023

10. Date of first revision of the text:
09/2021

11. Date of last revision of text:
20/11/2025

12. Instructions for Preparation of Radiopharmaceuticals (If Applicable):
Not Applicable.