For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Cefpodoxime Proxetil Oral Suspension IP

(Brand Name: CEDON® Drops / CEDON® Dry Syrup / CEDON®-DS Dry Syrup)

2. Qualitative and Quantitative Composition

CEDON Drops

Each Combipack Contains:

A) Cefpodoxime Proxetil Oral Suspension IP

Each ml (approximately 20 drops) of reconstituted suspension contains:

Cefpodoxime Proxetil IP equivalent to Cefpodoxime ……..…. 50 mg.

Excipients ……..… q.s.

B) Sterile Water for Injections IP ……..….. 10 ml.

CEDON Dry Syrup

Each Combipack Contains:

A) Cefpodoxime Proxetil Oral Suspension IP

Each 5 ml of reconstituted suspension contains:

Cefpodoxime Proxetil IP equivalent to Cefpodoxime …….. 50 mg.

Excipients …….. q.s.

B) Sterile Water for Injections IP ……..….. 25 ml.

CEDON-DS Dry Syrup

Each Combipack Contains:

A) Cefpodoxime Proxetil Oral Suspension IP

Each 5 ml of reconstituted suspension contains:

Cefpodoxime Proxetil IP equivalent to Cefpodoxime ……..…..… 100 mg.

Excipients ……....…. q.s.

B) Sterile Water for Injections IP ……..…….. 25 ml.

3. Dosage Form and Strength

Dosage Form: Oral Suspension.

Dosage Strength: Cefpodoxime 50 mg per ml; Cefpodoxime 50 mg per 5 ml; Cefpodoxime 100 mg per 5 ml.

4. Clinical Particulars

4.1 Therapeutic Indication

CEDON (Cefpodoxime proxetil) is indicated for the treatment of following infections when caused by susceptible bacteria:

- Acute otitis media.
- Pharyngitis and/or tonsillitis.
- Community-acquired pneumonia.
- Acute bacterial exacerbation of chronic bronchitis.
- Uncomplicated skin and skin structure infections.
- Acute maxillary sinusitis.
- Uncomplicated urinary tract infections such as cystitis and pyelonephritis.
- Typhoid fever.
- Acute, uncomplicated urethral and cervical gonorrhea and rectal gonococcal infections.

4.2Posology and Method of Administration

For oral administration.

Dosage in Infants and Paediatric Patients (age 2 months to 12 years)

- **Usual Dose:** 10 mg/kg/day in equally divided doses every 12 hours (i.e., 5 mg/kg/dose twice daily).
- **Dosage in Typhoid Fever:** 16 mg/kg/day in equally divided doses every 12 hours.

In children, for any indication, maximum daily dose of cefpodoxime should not exceed 400 mg.

Table: CEDON (Cefpodoxime) Dosage Recommendation in Paediatric Patients

Age	**Body Weight***	**Cefpodoxime Dose: 5 mg/kg/dose**		
		CEDON Drops (50 mg/ml, approximately 20 drops/ml)	CEDON Dry Syrup (50 mg/5 ml)	CEDON-DS Dry Syrup (100 mg/5ml)
2 to 6 months	5.4 kg	0.5 ml (10 drops) BID	2.5 ml BID	-
6 months to 1 year	8.4 kg	0.8 ml (16 drops) BID	4 ml BID	2 ml BID

1 to 3 year	12.9 kg	1.3 ml (26 drops) BID	6.5 ml BID	3.25 ml BID
4 to 6 year	18 kg	-	9 ml BID	4.5 ml BID
7 to 9 year	25.1 kg	-	-	6.25 ml BID
10 to 12 year	34.3 kg	-	-	8.5 ml BID

** Values for average body weight for respective age group have been obtained from reports of National Institute of Nutrition, ICMR, Hyderabad 2010.*

Dosage in Adults and Adolescents (age 12 years and older)

- **Usual Dose:** 200 to 400 mg per day in equally divided doses every 12 hours.
- **Skin and Skin Structure Infection:** 400 mg twice daily.
- **Gonorrhea and Rectal Gonococcal Infections:** 200 mg single dose.

Duration of therapy is 5 to 10 days depending on type and severity of infection. Cefpodoxime proxetil may be administered regardless of meal; however, administration with food results in increased absorption.
Or, as prescribed by the physician.

Directions for Reconstitution of CEDON Drops

Shake the bottle well to loosen the powder. Twist and open the vial of sterile water for injections IP - SWFI (supplied with this combipack). Then, open the bottle and add sterile water for injection up to the mark on the label and shake well. Replace the cap. Invert the bottle and shake vigorously so that water rises through the powder.
Adjust the volume up to the mark (to make 10 ml of reconstituted suspension) by adding more water, if necessary. Then, turn the bottle upright and shake vigorously for about a minute.
Use the reconstituted suspension within 14 days. Discard the unused portion of reconstituted suspension, if any, after 14 days.

Directions for Reconstitution of CEDON Dry Syrup / CEDON-DS Dry Syrup

Shake and tap the bottle to loosen the powder. Twist and open the vial of sterile water for injections IP - SWFI (supplied with this combipack). Then, open the bottle and add about half quantity of SWFI in to it. Close the bottle and shake vigorously. Adjust the volume up to the ring mark (to make 30 ml of reconstituted suspension) on the bottle by adding more SWFI, if necessary. Replace the cap, invert the bottle and shake vigorously so that water rises through the powder. Then, turn the bottle upright and shake vigorously for about a minute. Use the

reconstituted suspension within 7 days. Discard the unused portion of reconstituted suspension, if any, after 7 days.

Usage and Storage of Reconstituted Suspension

- Keep bottle tightly closed.
- Shake the reconstituted suspension well before each use.
- Replace cap securely after each opening.
- Store the reconstituted suspension in a refrigerator between 2 to 8 °C (36 to 46 °F).

4.3Contraindications

CEDON (Cefpodoxime proxetil) is contraindicated in patients with:

- Hypersensitivity to cefpodoxime or to other cephalosporin class antibiotics or to any excipient of the formulation.
- Previous history of immediate and/or severe hypersensitivity reactions (anaphylaxis) to penicillin or other beta-lactam antibiotic.

4.4Special Warnings and Precautions for Use

Hypersensitivity: Before therapy with cefpodoxime proxetil is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefpodoxime, other cephalosporins, penicillins, or other drugs. If an allergic reaction to cefpodoxime proxetil occurs, discontinue the drug. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, and airway management, as clinically indicated.

***Clostridium Difficile*-Associated Diarrhea:** *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cefpodoxime proxetil, 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. Clostridium difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains 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 antibiotic use. 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 use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

A concerted effort to monitor for *C. difficile* in cefpodoxime-treated patients with diarrhea was undertaken because of an increased incidence of diarrhea associated with *C. difficile* in early trials in normal subjects. *Clostridium difficile* organisms or toxin was reported in 10% of the

cefpodoxime-treated adult patients with diarrhea; however, no specific diagnosis of pseudomembranous colitis was made in these patients. Cefpodoxime proxetil should always be prescribed with caution in patients with a history of gastrointestinal (GI) disease, particularly colitis.

Superinfection: As with other antibiotics, prolonged use of cefpodoxime proxetil may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Antibiotic Resistance: Prescribing cefpodoxime in the absence of a proven or strongly suspected bacterial infection or as a prophylaxis therapy is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefpodoxime and other antibacterial drugs, CEDON should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Risk of Neutropenia: As with all beta-lactam antibiotics, neutropenia and more rarely agranulocytosis may develop particularly during extended treatment. For cases of treatment lasting longer than 10 days, the blood count should be monitored and treatment discontinued if neutropenia is found.

Renal Dysfunction: In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of cefpodoxime proxetil should be reduced because high and prolonged serum antibiotic concentrations can occur in such individuals following usual doses. Changes in renal function have been observed with cephalosporin antibiotics, particularly when given concurrently with potentially nephrotoxic drugs such as aminoglycosides and/or potent diuretics. In such cases, cefpodoxime proxetil should be used with caution and renal function should be monitored as and when required.

4.5Drug Interactions

Antacids/H_2-Antagonists: Studies have shown that the bioavailability is decreased by approximately 30% when cefpodoxime is administered with drugs which neutralize gastric pH or inhibit acid secretions. Therefore, antacids (such as aluminum hydroxide and sodium bicarbonate) and H_2 blockers (such as ranitidine), which can cause an increase in gastric pH, should be taken 2 to 3 hours after cefpodoxime administration.

Propantheline: Oral anti-cholinergics (e.g., propantheline) delay peak plasma levels (47% increase in T_{max}), but do not affect the extent of absorption (AUC).

Probenecid: As with other beta-lactam antibiotics, renal excretion of cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC and 20% increase in peak cefpodoxime plasma levels. Thus, co-administration of probenecid with cefpodoxime proxetil is not recommended.

Nephrotoxic Drugs: Although nephrotoxicity has not been reported when cefpodoxime proxetil was given alone, close monitoring of renal function is advised when cefpodoxime is administered concomitantly with drugs having nephrotoxic potential.

Oral Anticoagulants: Simultaneous administration of cefpodoxime with warfarin may augment its anti-coagulant effects. There have been many reports of increases in oral anti-coagulant activity in patients receiving antibacterial agents, including cephalosporins. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of the cephalosporins to the increase in international normalised ratio (INR) is difficult to assess. It is recommended that the INR should be monitored frequently during and shortly after co-administration of cefpodoxime with an oral anti-coagulant agent.

Oral Contraceptives: Cephalosporins reduces the contraceptive effect of estrogen derivatives. It is advised that patients to consider alternative supplementary (non-hormonal) contraceptive measures during treatment with cefpodoxime proxetil.

Drug/Laboratory Test Interactions

1. Cephalosporins, including cefpodoxime proxetil, are known to occasionally induce a positive direct Coombs' test.
2. 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.

4.6Use in Special Populations

Pregnant Women

Pregnancy Category B. Cefpodoxime proxetil was neither teratogenic nor embryocidal when administered to rats during organogenesis at doses up to 100 mg/kg/day (2 times the human dose based on mg/m^2) or to rabbits at doses up to 30 mg/kg/day (1 to 2 times the human dose based on mg/m^2). There are, however, no adequate and well-controlled studies of cefpodoxime proxetil use in pregnant women. Because animal reproduction studies are not always predictive of human response, cefpodoxime proxetil should be used during pregnancy only if clearly needed.

Lactating Women

Cefpodoxime is excreted in human milk. Because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Patients

Safety and efficacy of cefpodoxime proxetil in infants less than 2 months of age has not been established. For use and dosage in infants and children above 2 months, please refer ‘Posology and Method of Administration’ section.

Geriatric Patients

Elderly patients with normal renal function may be given the same dose as recommended for adults. No overall differences in effectiveness or safety were observed between the elderly and younger patients.

Renal Impairment Patients

Elimination of cefpodoxime is reduced in patients with moderate to severe renal impairment (creatinine clearance < 50 ml/min).

- For patients with severe renal impairment (creatinine clearance < 30 ml/min), the dosing intervals should be increased to every 24 hours.
- In patients with creatinine clearance < 10 ml/min, dosage to be administered every 48 hours.
- In patients maintained on hemodialysis, the dosing frequency is 3 times/week or one single dose after each dialysis session.

Hepatic Impairment Patients (Cirrhosis)

Absorption of cefpodoxime was found to be decreased while excretion becomes unchanged in patients with liver cirrhosis. The mean cefpodoxime t½ and renal clearance in cirrhotic patients were similar to those of healthy subjects. Ascites did not appear to affect values in cirrhotic subjects. No dosage adjustment of cefpodoxime proxetil is required in this patient population.

4.7Effect on Ability to Drive and Use Machines

Dizziness has been reported during treatment with cefpodoxime. Patients should know how they react to this drug therapy before they drive or operate machinery. If affected, patient should not engage in those activities requiring mental alertness such as driving a vehicle or operating machineries.

4.8Undesirable Effects

Clinical Trials Experience

Cefpodoxime proxetil is generally well tolerated. Adverse events possibly or probably related to cefpodoxime proxetil for oral suspension in multiple-dose clinical trials were:

1) Incidence Greater Than 1%

Gastrointestinal (GI): Diarrhea (6.0%), diarrhea in infants and toddlers of age 1 month to 2 years (12.8%), vomiting (2.3%).

Skin: Diaper rash/fungal skin rash includes moniliasis (2.0%), diaper rash in infants and toddlers (8.5%), other skin rashes (1.8%).

2) Incidence Less Than 1%

Body as a Whole: Localized abdominal pain, abdominal cramp, headache, monilia, generalized abdominal pain, asthenia, fever, fungal infection.

Digestive: Nausea, monilia, anorexia, dry mouth, stomatitis, pseudomembranous colitis.

Hemic and Lymphatic: Thrombocythemia, positive direct Coombs' test, eosinophilia, leukocytosis, leukopenia, prolonged partial thromboplastin time, thrombocytopenic purpura.
Metabolic and Nutritional: Increased alanine aminotransferase (ALT).
Musculo-Skeletal: Myalgia.
Nervous: Hallucination, hyperkinesia, nervousness, somnolence.
Respiratory: Epistaxis, rhinitis.
Skin: Skin moniliasis, urticaria, fungal dermatitis, acne, exfoliative dermatitis, maculopapular rash.
Special Senses: Taste perversion.

Post-Marketing Experience

The following serious adverse experiences have been reported: Allergic reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme and serum sickness-like reactions, pseudomembranous colitis, bloody diarrhea with abdominal pain, ulcerative colitis, rectorrhagia with hypotension, anaphylactic shock, acute liver injury, in utero exposure with miscarriage, purpuric nephritis, pulmonary infiltrate with eosinophilia, and eyelid dermatitis. One death was attributed to pseudomembranous colitis and disseminated intravascular coagulation.

Adverse Reactions of Cephalosporin-Cass Antibiotics

The following adverse reactions and altered laboratory tests have been reported for cephalosporin class antibiotics: Renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, serum sickness-like reaction, hemorrhage, agranulocytosis, pancytopenia and fixed drug eruption (FDE). Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

Laboratory Abnormalities

Most of the altered laboratory values are transient and not clinically significant. Significant laboratory changes that have been reported in adult and paediatric patients in clinical trials of cefpodoxime proxetil, without regard to drug relationship were:
Hepatic: Transient increases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), alkaline phosphatase, bilirubin, and lactate dehydrogenase (LDH).
Hematologic: Eosinophilia, leukocytosis, lymphocytosis, granulocytosis, basophilia, monocytosis, thrombocytosis, decreased hemoglobin, decreased hematocrit, leukopenia, neutropenia, lymphocytopenia, thrombocytopenia, thrombocythemia, positive Coombs' test, prolonged prothrombin time (PT), and partial thromboplastin time (PTT).

Serum Chemistry: Hyperglycemia, hypoglycemia, hypoalbuminemia, hypoproteinemia, hyperkalemia, and hyponatremia.
Renal: Increase in blood urea nitrogen (BUN) and creatinine.

4.9Overdose

Symptoms: The toxic symptoms following an overdose of beta-lactam antibiotics may include nausea, vomiting, epigastric distress, and diarrhea. In cases of overdose, particularly in patients with renal insufficiency, encephalopathy may occur. The encephalopathy is usually reversible once cefpodoxime plasma levels have fall down.
Treatment: In the event of overdose with cefpodoxime, supportive and symptomatic therapy is indicated. If serious toxic reaction from overdose occurs, hemodialysis or peritoneal dialysis may aid in the removal of cefpodoxime from the body, particularly if renal function is compromised.

5. Pharmacological Properties

5.1 Mechanism of Action

Cefpodoxime proxetil is a prodrug; its active metabolite is cefpodoxime. Cefpodoxime is 3rd generation oral cephalosporin class of beta-lactam antibiotic.
Cefpodoxime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death (bactericidal effect). Cefpodoxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of gram-negative and gram-positive bacteria.

5.2Pharmacodynamic Properties

Cefpodoxime produces antibacterial effect. Cefpodoxime has been shown to be active against most isolates of the following bacteria, both *in vitro* and in clinical infections:

Gram-Positive Bacteria

- *Staphylococcus aureus* (methicillin-susceptible strains).
- *Staphylococcus saprophyticus.*
- *Streptococcus pneumoniae* (excluding penicillin-resistant isolates).
- *Streptococcus pyogenes.*

Gram-Negative Bacteria

- *Escherichia coli.*
- *Klebsiella pneumonia.*
- *Proteus mirabilis.*
- *Haemophilus influenzae* (including beta-lactamase producing isolates).
- *Moraxella catarrhalis.*
- *Neisseria gonorrhoeae* (including penicillinase-producing isolates).

The following *in vitro* data are available, but their clinical significance is unknown. At least 90% of the following microorganisms exhibit an *in vitro* minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for cefpodoxime. However, the efficacy of cefpodoxime in treating clinical infections due to these microorganisms has not been established in adequate and well-controlled clinical trials.

Gram-Positive Bacteria

- *Streptococcus agalactiae.*
- Streptococcus species (Groups C, F, G).

Gram-Negative Bacteria

- *Citrobacter diversus.*
- *Klebsiella oxytoca.*
- *Proteus vulgaris.*
- *Providencia rettgeri.*
- *Haemophilus parainfluenzae.*

Anaerobic Gram-Positive Bacteria

- *Peptostreptococcus magnus.*

5.3Pharmacokinetic Properties

Over the recommended dosing range (100 to 400 mg), the rate and extent of cefpodoxime absorption is dose-dependent. In patients with normal renal function, neither accumulation nor significant changes in other pharmacokinetic parameters were noted following multiple oral dosage of up to 400 mg every 12 hours.

Absorption: Cefpodoxime proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, cefpodoxime. Following oral administration of 100 mg of cefpodoxime proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. The extent of absorption (mean AUC) and the mean peak plasma concentration increased when cefpodoxime proxetil were administered with food. Over the recommended dosing range, the T_{max} was approximately 2 to 3 hours. Mean C_{max} was 1.4 mcg/ml for the 100 mg dose, 2.3 mcg/ml for the 200 mg dose, and 3.9 mcg/ml for the 400 mg dose.

Distribution: The volume of distribution of cefpodoxime is 32.3 liters. Plasma protein binding of cefpodoxime ranges from 21 to 29%. Concentrations of cefpodoxime in excess of the minimum inhibitory concentration (MIC) for common pathogens can be achieved in lung parenchyma, bronchial mucosa, pleural fluid, tonsils, interstitial fluid and prostate tissue.

Metabolism: There is minimal metabolism of cefpodoxime *in vivo*.

Excretion: Cefpodoxime is primarily excreted by renal route; 80% is excreted unchanged in the urine, with an elimination half-life of approximately 2.4 hours.

Pharmacokinetic Data in Paediatric Population

In children, studies have shown the maximum plasma concentration occurs approximately 2 to 4 hours after dosing. A single 5 mg/kg dose in 4 to 12 year old children produces a maximum concentration similar to that in adults (200 mg dose). In patients below 2 years receiving repeated doses of 5 mg/kg 12 hourly, the average plasma concentrations, 2 hours post dose, are between 2.7 mg/l (1 to 6 months) and 2.0 mg/l (7 months to 2 years).

In patients between 1 month and 12 years receiving repeated doses of 5 mg/kg 12 hourly, the residual plasma concentrations at steady state are between 0.2 to 0.3 mg/l (1 month to 2 years) and 0.1 mg/l (2 to 12 years).

6. Nonclinical Properties

6.1 Animal Toxicology

Acute toxicity: The median lethal dose in mice and rats was above 8 g/kg and 4 g/kg bodyweight, respectively. In Fisher rats doses of 1 g/kg body weight and higher influenced stool consistency and weight gain. Single doses of 800 mg/kg body weight were non-toxic in dogs.

Repeat-dose toxicity: Chronic toxicity studies were carried out over 12 months in rats and 6 months in dogs. Maximum daily doses (1000 mg/kg body weight orally in rats and 400 mg/kg orally in dogs) were considerably higher than recommended therapeutic doses (3-8 mg/kg body weight). No mortality was observed in rats receiving 250, 500 or 1000 mg/kg for 12 months. Only at 1000 mg/kg, effects on the GI-tract, softened stools and dilatation of the caecum were observed. Intestinal side effects, which were more pronounced in Fisher rats, are due to the change in intestinal flora caused by the pronounced antibacterial effect of cefpodoxime. Daily administration of 0, 25, 100, and 400 mg/kg body weight to dogs did not reveal mortality. Unchanged cefpodoxime was detected in faeces.

Carcinogenesis: Long-term animal carcinogenesis studies of cefpodoxime proxetil have not been performed.

Mutagenesis: Mutagenesis studies of cefpodoxime, including the Ames test both with and without metabolic activation, the chromosome aberration test, the unscheduled DNA synthesis assay, mitotic recombination and gene conversion, the forward gene mutation assay and the in vivo micronucleus test, were all negative.

Impairment of fertility: No untoward effects on fertility or reproduction were noted when 100 mg/kg/day or less (2 times the human dose based on mg/m^2) was administered orally to rats.

Teratogenicity: Cefpodoxime proxetil was neither teratogenic nor embryocidal when administered to rats during organogenesis at doses up to 100 mg/kg/day (2 times the human dose based on mg/m^2) or to rabbits at doses up to 30 mg/kg/day (1-2 times the human dose based on mg/m^2).

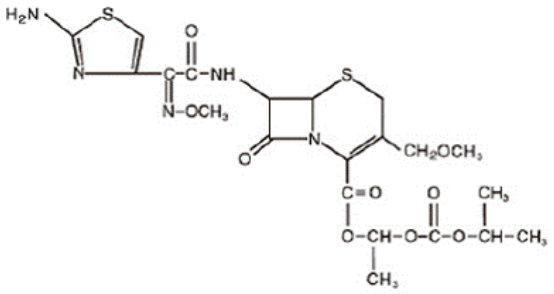
7. Description

CEDON Drops is off white free flowing powder filled in amber colour glass bottle.

CEDON Dry Syrup is White to off white granular free flowing powder filled in HDPE labeled bottle.
CEDON-DS Dry Syrup is White to off white granular free flowing powder filled in HDPE labeled bottle.

CEDON Drops contain 50 mg of cefpodoxime per ml of reconstituted suspension for oral administration.
CEDON Dry Syrup contains 50 mg of cefpodoxime per 5 ml of reconstituted suspension for oral administration.
CEDON-DS Dry Syrup contains 100 mg of cefpodoxime per 5 ml of reconstituted suspension for oral administration.

Cefpodoxime proxetil is a prodrug; its active metabolite is cefpodoxime. Cefpodoxime proxetil is an orally administered, extended spectrum, semi-synthetic, 3rd generation cephalosporin class of beta-lactam antibiotic.
Cefpodoxime proxetil appears as almost white to pale yellow coloured powder.
Molecular Weight: 557.6 g/mol.
Molecular Formula: $C_{21}H_{27}N_5O_9S_2$.
Chemical Name: (RS)-1(isopropoxycarbonyloxy) ethyl (+)-(6R,7R)-7-[2-(2-amino-4-thiazolyl)-2-{(Z)methoxyimino}acetamido]-3-methoxymethyl-8-oxo-5-thia-1-azabicyclo [4.2.0]oct-2-ene-2-carboxylate.
Structural Formula:



Inactive ingredients (excipients) of CEDON Drops contain Colloidal Silicon Dioxide, Butylated Hydroxy Anisole, Flavour Capsaroma Mango, Sucrose, Sodium CMC, Sodium Benzoate, Sodium Citrate, Citric Acid (Anhydrous), Saccharine Sodium, Flavour Peppermint & Sodium Lauryl Sulphate.

Inactive ingredients (excipients) of CEDON Dry Syrup contain Colloidal Silicon Dioxide, Butylated Hydroxy Anisole, Flavour Capsaroma Mango, Sucrose, Sodium CMC, Sodium Benzoate, Sodium Citrate, Citric Acid (Anhydrous) & Saccharine Sodium.

Inactive ingredients (excipients) of CEDON-DS Dry Syrup contain Colloidal Silicon Dioxide, Butylated Hydroxy Anisole, Flavour Mango, Neotame, Sucrose, Sodium Benzoate, Sodium CMC, Sodium Citrate & Citric Acid (Anhydrous).

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

18 Months

8.3Packaging Information

CEDON Drops: Combipack of 10 ml amber colour glass bottle with calibrated dropper and one FFS ampoule of 10 ml sterile water for reconstitution.

CEDON Dry Syrup: Combipack of 30 ml HDPE bottle with measuring cup and one FFS ampoule of 25 ml sterile water for reconstitution.

CEDON-DS Dry Syrup: Combipack of 30 ml HDPE bottle with measuring cup and one FFS ampoule of 25 ml sterile water for reconstitution.

8.4Storage and Handling Instructions

Store protected from light and moisture, at a temperature not exceeding 30°C.

Keep out of reach of children.

Store reconstitution suspension in a refrigerator between 2 °C to 8 °C and use the same within 7 days.

9. Patient Counseling Information

Administration Instructions to Patients / Caregivers

- Patients/caregivers should be counseled that antibacterial drugs should only be used to treat bacterial infections; not to use this medicine to treat infections caused by viruses (such as common cold).
- Patients/caregivers should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the treatment and increase the likelihood of developing antibiotic resistance.

- Inform patients/caregivers that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterials, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibacterial. If this occurs, patients should inform their physician as soon as possible.
- This medicine should be avoided in children below 2 months of age.
- Pregnant women should consult their doctor before use of this medicine.
- Lactating mothers are advised not take this medicine or if medicine is essential, no to breastfeed their child while on drug therapy.
- Shake suspension well before each use. Use reconstituted suspension within 14 days; thereafter, unused portion, if any, should be discarded.

10. Details of Manufacturer

Malik Lifesciences Pvt. Ltd.
(A subsidiary of Akums Drugs & Pharmaceutical Ltd.)
Plot No. – 16, Vardhman Industrial Estate, N.H. 58,
Haridwar – 247 667, Uttarakhand.

11. Details of Permission or License Number with Date

CEDON Drops: Mfg. Lic No. : 48/UA/SC/P- 2013.Date of FDA product permission 28/02/2018

CEDON Dry Syrup: Mfg. Lic No. : 48/UA/SC/P- 2013.Date of FDA product permission 03/06/2015

CEDON-DS Dry Syrup: Mfg. Lic No. : 48/UA/SC/P- 2013. Date of FDA product permission 03/06/2015

12. Date of Revision

September 2022.

Marketed by:
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Division of
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