

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 Tablets IP

(Brand Name: CEDON[®]-100 DT / 200 DT)

2. Qualitative and Quantitative Composition

Each dispersible uncoated tablet contains:

Cefpodoxime Proxetil IP equivalent to Cefpodoxime 100 mg /200 mg.

Excipients q.s.

3. Dosage Form and Strength

Dosage Form: Dispersible Tablets.

Dosage Strength: Cefpodoxime 100 mg per tablet ; Cefpodoxime 200 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

CEDON Dispersible Tablets are 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 gonorrhoea and rectal gonococcal infections.

4.2 Posology and Method of Administration

For oral administration.

Dosage in Infants and Paediatric Patients (Age 2 Months to 12 Years)

1) Dosage Based on Body Weight

- **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.

2) Usual Dosage Based on Age Group

CEDON-100 DT

- **4 to 6 years (16 to 20 kg):** 1 tablet twice daily.
- **6 to 12 years (20 to 40 kg):** 1 to 2 tablets twice daily.

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

CEDON-200 DT

Dosage in Adults and Adolescents

- **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 Dispersible Tablets

CEDON-100 and CEDON-200 Dispersible Tablets should be reconstituted by the addition of adequate amount of clean potable water (5 to 10 ml) immediately before use. Stir well until the tablet gets properly dispersed in the water and then swallow orally.

4.3 Contraindications

CEDON Dispersible Tablets are 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.

4.4 Special 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.

4.5 Drug Interactions

Antacids/H₂-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 H₂ 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.

4.6 Use 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/m²) or to rabbits at doses up to 30 mg/kg/day (1 to 2 times the human dose based on mg/m²). 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 of age, 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 t_{1/2} 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.

4.7 Effect 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.

4.8 Undesirable Effects

Clinical Trials Experience

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

A. Incidence Greater Than 1%

- Diarrhea (7.0%) - Diarrhea or loose stools were dose-related decreasing from 10.4% of patients receiving 800 mg per day to 5.7% for those receiving 200 mg per day.
- Nausea (3.3%).
- Vaginal fungal infections (1.0%).
- Vulvovaginal infections (1.3%).
- Abdominal pain (1.2%).
- Headache (1.0%).

B. Incidence Less Than 1%

Body as a Whole: Fungal infections, abdominal distention, malaise, fatigue, asthenia, fever, chest pain, back pain, chills, generalized pain, abnormal microbiological tests, moniliasis, abscess, allergic reaction, facial edema, bacterial infections, parasitic infections, localized edema, localized pain.

Cardiovascular: Congestive heart failure, migraine, palpitations, vasodilation, hematoma, hypertension, hypotension.

Digestive: Vomiting, dyspepsia, dry mouth, flatulence, decreased appetite, constipation, oral moniliasis, anorexia, eructation, gastritis, mouth ulcers, gastrointestinal disorders, rectal disorders, tongue disorders, tooth disorders, increased thirst, oral lesions, tenesmus, dry throat, toothache.

Hemic and Lymphatic: Anemia.

Metabolic and Nutritional: Dehydration, gout, peripheral edema, weight gain.

Musculo-skeletal: Myalgia.

Nervous: Dizziness, insomnia, somnolence, anxiety, shakiness, nervousness, cerebral infarction, change in dreams, impaired concentration, confusion, nightmares, paresthesia, vertigo.

Respiratory: Asthma, cough, epistaxis, rhinitis, wheezing, bronchitis, dyspnea, pleural effusion, pneumonia, sinusitis.

Skin: Urticaria, rash, pruritus, diaphoresis, maculopapular rash, fungal dermatitis, desquamation, dry skin, hair loss, vesiculobullous rash, sunburn.

Special Senses: Taste alterations, eye irritation, taste loss, tinnitus.

Urogenital: Hematuria, urinary tract infections, metrorrhagia, dysuria, urinary frequency, nocturia, penile infection, proteinuria, vaginal pain.

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-Class 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.

4.9 Overdose

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.

5.2 Pharmacodynamic 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 pneumoniae*.
- *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*.

5.3 Pharmacokinetic 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/m²) 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/m²) or to rabbits at doses up to 30 mg/kg/day (1-2 times the human dose based on mg/m²).

7. Description

CEDON-100 Tablets are off white, round, flat faced, beveled edged, uncoated tablet with breakline on one side and plain on other side and having mango flavour.

CEDON-200 Tablets are off white, capsule shaped uncoated tablets with breakline on one side and plain on other side and having mango flavour.

CEDON-100 Dispersible Tablets contain 100 mg of cefpodoxime for oral administration.

CEDON-200 Dispersible Tablets contain 200 mg of cefpodoxime 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.

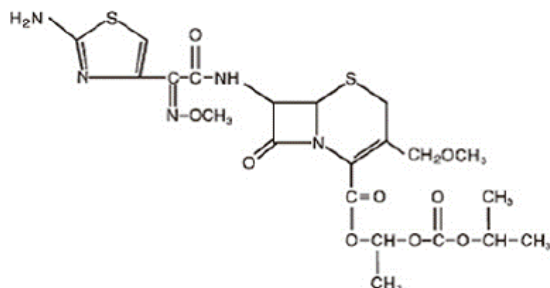
Cefpodoxime proxetil appears as almost white to pale yellow coloured powder.

Molecular Weight: 557.6 g/mol.

Molecular Formula: C₂₁H₂₇N₅O₉S₂.

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-100 Dispersible Tablet contain Microcrystalline Cellulose, Sodium Lauryl Sulphate, Hydrogenated Castor Oil, Croscarmellose Sodium, Colloidal Silicon Dioxide, Magnesium Stearate, Talc, Saccharin Sodium, Flavour Magna Sweet, Flavour Mango & Flavour BTM Mint.

Inactive ingredients (excipients) of CEDON-200 Dispersible Tablet contain Microcrystalline Cellulose, Sodium Lauryl Sulphate, Hydrogenated Castor Oil, Croscarmellose Sodium, Colloidal Silicon Dioxide, Magnesium Stearate, Talc, Saccharin Sodium, Flavour Magna Sweet, Flavour Mango & Flavour BTM Mint.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2 Shelf-life

18 Months

8.3 Packaging Information

10 tablets per strip.

8.4 Storage and Handling Instructions

Store protected from light and moisture, at a temperature not exceeding 25°C.

Keep out of reach of children.

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.
- Remove tablet from its original packing just before its use. Disperse the tablet in 5 to 10 ml of water and then swallow orally.

10. Details of Manufacturer

Blue Cross Laboratories Pvt. Ltd.

A – 12, MIDC, Ambad, Nashik – 422 010 Maharashtra.

11. Details of Permission or License Number with Date

CEDON 100 DT: Mfg. Lic. No. : BD/28. Date of FDA Product Permission: 18/09/2007

CEDON 200 DT: Mfg. Lic. No. : BD/28. Date of FDA Product Permission: 18/09/2007

12. Date of Revision

September 2022.

Marketed by:



Division of BLUE CROSS

MADE IN INDIA BY

BLUE CROSS LABORATORIES PVT LTD.

A-12, M.I.D.C., NASHIK-422 010.

Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.