# SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the medicinal product: Brand Name:**
   CELZA 500
   Generic Name: Cefuroxime 500 mg

2. **Qualitative and Quantitative Composition**
   Each film coated tablet contains:
   Active Ingredient:
   Cefuroxime Axetil USP.....500mg

   Excipients with known effect:
   Sodium Lauryl sulfate....9mg

   For the full list of excipients, see section 6.1.

3. **Pharmaceutical form:**

   Oral film coated tablet.

   **Description:** White to off white coloured, capsule shape, standard biconvex and film coated tablets plain on both sides.

4. **Clinical particulars:**

**4.1 Therapeutic indications:**

**CELZA 500** is indicated for the treatment of infections caused by susceptible strains of the following organisms in the following infections:

- Pharyngitis and tonsilitis caused by Streptococcus pyogenes.
- Otitis media caused by Streptococcus pneumoniae, Haemophilus influenzae (ampicillin- sensitive and resistant strains), Moraxella (Branhamella) catarrhalis and Streptococcus pyogenes.
- Sinusitis caused by Streptococcus pneumoniae and Haemophilus influenzae. Acute and chronic bronchitis caused by Steptococcus pneumoniae, Haemophilus influenzae (ampicillin-sensitive and resistant strains**)** and Haemophilus parainfluenzae (ampicillin- sensitive and resistant strains**).**
- Acute uncomplicated cystitis caused by Escherichia coli and Klebsiella pneumoniae.
- Lyme disease caused by Borrelia burgdorferi.

**4.2 Posology and method of administration: Adults:**
**Sinusitis & acute or chronic bronchitis:**

250 mg twice daily for seven days (Range 5-10 days)

**Acute uncomplicated cystitis:**

125 mg twice daily for seven days (Range 5-10 days)

**Lyme disease:**

Adults and children over 12 years of age: 500 mg twice daily for 20 days.

**Children:**

There is no experience with CELZA 500 in children under 3 months of age. 3 months to 2 years of age: 125 mg twice daily
Over 2 years of age: 250 mg twice daily.

CELZA 500 shoul be taken after food for optimum absorption.

## 4.3 Contraindications

Hypersensitivity to Cephalosporin antibiotics or to any components of the formulation. Hypersensitivity to penicillin and other beta-lactam antibiotics.

## 4.4 Special warnings and precautions for use:

**Warning:**

CELZA 500 should be used with caution in patients with:

- A history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- Renal function impairment – A reduced dose may be required.
- Porhyria: Safety has not been established.

Pseudomembranous colitis may occur. Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and wayery diarrhoea (which may be bloody) and fever, should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, CELZA 500 shoul be stopped immediately and appropriate therapy initiated.

**Special precaution:**

Prolonged use of CELZA 500 may also result in the overgrowth of other non-susceptible microorganisms (e.g. enterococci and Clostridium difficile).
Pseudomembranous colitis have been observe with the use of CELZA 500. Patients who develop abdominal or stomach cramps nearly all antibacterial agents, including cefuroxime and may range in severity from mild to life threatening.
The Jarisch-Herxheimer reaction has been seen observed following treatment with CELZA 500 for Lyme disease. This reaction is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease

## 4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of probenecid increases the area under the mean serum concentration time -Curve by 50%.
Interactions with Laboratory Tests:

It is recommended that either glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving CELZA 500. This medicine may give false -negative results with ferricyanide blood glucose

test. CELZA 500 does not interfere in the alkaline picrate assay for creatinine. A false-positive Coombs reaction may appear in patients who receive large doses of CELZA 500.

### 4.6 Pregnancy and lactation

Safety and efficacy in pregnancy and latation have not been established.

### 4.7 Effects on ability to drive and use machines

Not Known

### 4.8 Undesirable effects

he most common adverse reactions are Candida overgrowth, eosinophilia, headache, dizziness, gastrointestinal disturbances and transient rise in liver enzymes.

The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data (for example from placebo-controlled studies) for calculating incidence were not available. In addition, the incidence of adverse reactions associated with cefuroxime axetil may vary according to the indication.

Data from large clinical studies were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e. those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than true frequency. Placebo-controlled trial data were not available. Where incidences have been calculated from clinical trial data, these were based on drug-related (investigator assessed) data. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Treatment related adverse reactions, all grades, are listed below by MedDRA body system organ class, frequency and grade of severity. The following convention has been utilised for the classification of frequency: 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 and not known (cannot be estimated from the available data).

| | |
|---|---|
| Hematological | Eosinophilia |
| Neurological | Headache |
| Gastrointestinal | Nausea, Vomiting, abdominal Pain, diarrhoea, in some cases accompanied by blood in stools, which may be a symptom of enterocolitis. A particular form of enterocolitis is pseudomembranous colitis. |
| Kidney/Genitourinary | Vaginal candidiasis |
| Liver | Transient increases in hepatic enzyme levels |
| Skin | Erythema multiforme, Stevens Johnson Syndrome, Toxic epidermal necrolysis |
| Other | Hypersensitivity reactions including skin rashes, |

| | |
|---|---|
| Urticaria | Pruritus, bronchospasm, drug fever, serum sickness, anaphylaxis |

Reporting of Adverse Drug Reactions

Healthcare professionals are asked to report any suspected adverse drug reactions via the Pharmacy and Poisons Board's; Pharmacovigilance-Electronic-Reporting-System (PvERS)https://pharmacyboardkenya.org

### 4.9 Overdose

Symptoms: Seizures heave been reported..
Treatment:
Treatment is symptomatic and supportive.Serum levels of CELZA 500 can be reduced by haemodialysis and peritoneal dialysis.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** Broad and medium spectrum antibiotics, ATC code: J01DC02

**Pharmacological Action:**

Cefuroxime is a bactericidal second generation cepalosporin. The antibacterial action of cefuroxime results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in Bacterial cytoplasmic membranes. Cefuroxime has bactericidal activity against a wide range of bacterial organisms, including beta lactamase producing strains.

### 5.2 Pharmacokinetic properties

Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolysed in the intestinal mucosa and blood to release cefuroxime into the plasma. Oral absorption is optimal when administered with food. Proteins binding is approximately 33 % to 5-
%. Cefuroxime is not metabolised and is excreted unchanged in the urine by glomelular filtration and tubular secretion. The elimination half life is between 1 and 1.5 hoursafter oral dosing. The elimination half life is prolonged with renal impairment. Serum levels of cefuroxime are reduced by dialysis.

## 6. Pharmaceutical particulars

### 6.1 List of excipients:

Microcrystalline Cellulose*
Hydrogenated Castor Oil
Croscarmellose Sodium (Disocel)
Sodium Lauryl Sulphate
HPMC

Colloidal Silicon Dioxide
Opadry White
Purified Water

### 6.2 Incompatibilities

Not Applicable

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Store in a dry place below 30° C. Protect from Light. Keep away from the reach of Children.

**6.5 Nature and contents of container**

10 tablets packed in ALU/ALU Blister and such 1 blister is packed in printed carton along with pack insert.

**6.6 Special precautions for disposal and other handling**

Not Applicable

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES**

**Marketing Authorisation Holder:**

**CACHET PHARMACEUTICALS PRIVATE LIMITED**

Address: 415, Shah Nahar Ind. Estate,

Dr. E. Moses Road, Worli, Mumbai-400 018 Maharashtra, India

**Manufacturer:**

**INNOVA CAPTAB LTD.**

1281/1, Hilltop, Industrial Estate, Near EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan,(H.P) INDIA

**8. MARKETING AUTHORISATION NUMBER**

H2015/CTD2535/096

**9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

Date of Re-registration: 31/03/2026

**10. DATE OF REVISION OF THE TEXT**

31/03/2026