# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Ceftinex (Cefdinir) 300mg FILM COATED TABLET

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains; 300 mg Cefdinir.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film coated tablet

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Ceftinex tablet is indicated for mentioned below;

- Pneumonitis of Community: caused by *Haemophilus influenzae* (including strains produced beta lactamase), *Haemophilus parainfluenzae* (including strains produced beta lactamase), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis*'in (including beta-lactamase producing strains).

- Acute Exacerbation of Chronic Bronchitis: caused by *Haemophilus influenzae* (including strains produced beta lactamase), *Haemophilus parainfluenzae* (including strains produced beta lactamase), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis*'in (including beta-lactamase producing strains).

- Acute Maxillary Sinusitis: caused by *Haemophilus influenzae* (including strains produced beta lactamase), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis* (including beta-lactamase producing strains).

- Angina/ Tonsillitis: caused by *Streptococcus pyogenes*.

- Uncomplicated Skin Infections: caused by *Staphylococcus aureus* (including beta-lactamase producing strains) and *Streptococcus pyogenes.*

### 4.2 Posology and method of administration

Dosage and treatment for adults and children with more than 13 years is presented below as table.

| Type of Infection | Dosage | Duration |
|---|---|---|
| Pneumonitis of Community | 300 mg per 12 hour period | 10 days |
| Acute Exacerbation of Chronic Bronchitis | 300 mg per 12 hour period<br>or<br>600 mg single daily dose | 5 to 10 days<br>10 days |
| Acute Maxillary Sinusitis | 300 mg per 12 hour period<br>or<br>600 mg single daily dose | 10 days<br>10 days |
| Angina/ Tonsillitis | 300 mg per 12 hour period<br>or<br>600 mg single daily dose | 5 to 10 days<br>10 days |
| Uncomplicated Skin Infection | 300 mg per 12 hour period | 10 days |

Daily dose should not exceed 600 mg.

Usage in the elderly: Dose adjustment in elderly patients is not necessary unless they are not having renal insufficiency.

Usage in patients with renal insufficiency: For adult patients with creatinine clearance < 30mL/min, the dose should be 300 mg given once daily. Hemodialysis removes cefdinir from the body. The recommended initial dosage is 300 mg (or 7 mg/kg) every other day. At the conclusion of each hemodialysis session, 300 mg (or 7 mg/kg) dose should be administrated. Subsequent doses should be 300 mg (or 7 mg/kg) every other day.

### 4.3 Contraindications

It is contraindicated in patients with known hypersensitivity to the cephalosporin class of antibiotics.

### 4.4 Special warnings and precautions for use

Before therapy with cefdinir, inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cefdinir, other cephalosporins, penicillins or other drugs. If cefdinir is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-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 cefdinir occurs, the drug should be discontinue. Serious acute hypersensitivity

reactions may require treatment with epinephrine and other emergency measures including intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines and airway management with oxygen.

Pseudomembranous colitis have been reported with nearly all antibacterial agent including cefdinir. Therefore, it is important to be careful in patients who present with diarrhea subsequent to the administration of antibacterial agents. Treatment with antibacterial agents alters the normal flora of colon. Studies indicate that a toxin produced by *Clostridium difficile* is a primary cause of antibiotic-associated colitis. After diagnosis of pseudomembranous colitis has been established, appropriate therapy should be initiated. Mild cases of Pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation and treatment with an antibacterial drug clinically effective against *Clostridium difficile*.

As with other broad-spectrum antibiotics, prolonged treatment may result overgrowth of resistant organisms. Careful observation of the patient is essential. If superinfection occurs, appropriate alternative therapy should be administrated.
Cefdinir, as with other broad-spectrum antibiotics, should be administrated carefully to the patients with a history of colitis.

In patients with renal insufficiency (creatinine clearance <30 mL/min), the dose of cefdinir should be adjusted.

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

Cefdinir should be taken at least 2 hours before or after the antiacid if it is used together with aluminum or magnesium containing antiacids.

As with other drugs, probenecid inhibits the renal excretion of cefdinir.
In the case of concomitant administration of cefdinir with iron containing drugs, cefdinir should be taken at least 2 hours before or after this drug.

### 4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women, therefore it should be used during pregnancy only if clearly needed.

Following administration of single 600 mg doses, was not detected in breast milk

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

Adverse effects on the ability to drive or operate machinery have not been observed.

### 4.8 Undesirable effects

The side effects after using cefdinir are mild and self-limited. Most common reported side effects are diarrhea, vaginal moniliasis, nausea, headache, abdominal pain and vaginitis.

IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

**INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:**

Cefdinir should be taken at least 2 hours before or after the antiacid if it is used together with aluminum or magnesium containing antiacids.

As with other drugs, probenecid inhibits the renal excretion of cefdinir.

In the case of concomitant administration of cefdinir with iron containing drugs, cefdinir should be taken at least 2 hours before or after this drug.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

### 4.9 Overdose

Information on cefdinir overdosage in humans is not available. Toxic signs and symptoms following overdosage with other beta-lactam antibiotics are nausea, vomiting, epigastric distress, diarrhea and convulsions. Hemodialysis removes cefdinir from the body.

## 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Ceftinex Film coated tablet contains the active ingredient cefdinir which is an extended-spectrum semisynthetic cephalosporin. Cefdinir, which is a third generation cephalosporin, reveals bactericidal effect by disrupting the synthesis of bacterial cell walls. Microorganisms resistant to penicillins and certain cephalosporins are sensitive to cefdinir. Cefdinir has more affinity to penicillin binding protein (PBP) 3,2,1 of *S. aureus* and penicillin binding protein (PBP) 2 and 3 of *E. faecalis* than the other cephalosporins. Cefdinir inhibits the myeloperoxidase excretion of neutrophils at the time of neutrophil stimulation by the mediators.

**Microbiology:**

It is revealed that cefdinir is effective on the microorganisms below:

Aerobic Gram-Positive Microorganisms:

*Staphylococcus aureus* (including beta-lactamase producing strains, excluding methicillin-resistant strains)

*Streptococcus pneumoniae* (penicillin- sensitive strains only)

*Streptococcus pyogenes*

*Staphylococcus epidermidis* (methicillin- sensitive strains only)

*Streptococcus agalactiae*

Streptococcus viridans species

Aerobic Gram-Negative Microorganisms:

*Haemophilus influenzae* (including beta-lactamase producing strains)

*Haemophilus parainfluenzae* (including beta-lactamase producing strains)

*Moraxella catarrhalis* (including beta-lactamase producing strains)

*Citrobacter diversus*

*Escherichia coli*

*Klebsiella pneumoniae*

*Proteus mirabilis*

## 5.2 Pharmacokinetic properties

Absorption:

Maximal plasma concentrations occur 2 to 4 hours postdose following oral administration. Cefdinir concentration in plasma increase with dosage, but these are not paralel with the range of dosage increases. Bioavailability of cefdinir is determined 21% after using 300 mg and 16% after 600 mg Cefdinir tablet.

After high-fat diet absorption of Cefdinir (Cmax) and amount (AUC) decreases respectively 16% and 10%. But this situation does not make sense for clinical. So Cefdinir can be taken independently of meals.

Following taken 300 mg cefdinir tablet Cmax (µg/ mL), tmax (hour) and AUC (µg. hour/ mL) value respectively are determined; 1.60, 2.9, 7.05 and following taken 600 mg cefdinir tablet; 2.87, 3.0, 11.1.

Multiple dosing: Cefdinir does not accumulate in plasma following once or twice daily administration to patients with normal renal functions.

Distribution:
The mean volume of distribution in children is 0.67 L/kg (±0.29). Cefdinir is 60% to 70% bound to plasma proteins in both adults and children; binding is independent of concentration.

Metabolism and excretion:
Cefdinir is not appreciably metabolised. It is eliminated via renal excretion with a mean plasma elimination half-life (t½) of 1.7 hours. Renal clearance is 2.0(±1.0) mL/min./kg. after taking 300 mg and 600 mg cefdinir tablet to patients with normal renal functions. The amount excreted unchanged in urine is respectively 18.4% (±6.4) and 11.6% (±4.6). Cefdinir clearance is reduced in patients with renal dysfunction. Because renal excretion is the predominant pathway of elimination, dosage should be adjusted in patients with renal function disorder or who are undergoing hemodialysis.

### 5.3 Preclinical safety data

Carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase (HGPRT) locus in V79 Chinese hamster lung cells. No clastogenic effects were observed in vitro in the structural chromosome aberration assay in V79 Chinese hamster lung cells or in vivo in the micronucleus assay in mouse bone marrow.

In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m2/day).

Cefdinir was not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m2/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/m2/day). Maternal toxicity (decreased body weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at ≥ 100 mg/kg/day, and in rat offspring at ≥ 32 mg/kg/day.

No effects were observed on maternal reproductive parameters, offspring survival, development, behavior, or reproductive functions.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium carboxymethyl cellulose
Microcrystalline cellulose
Polyoxyl stearate
Magnesium stearate
Colloidal anhydrous silica
Methocel
Titanium dioxide
Polyethyleneglycol

### 6.2 Incompatibilities

There are no incompatibilities between excipient-excipient or excipient – active ingredient or finished product – packaging material.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below30oC, at room temperature
Keep out of reach of children and in its original package.

### 6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Al/PVC/PE/PVDC blister in a cardboard box with its leaflet.

### 6.6 Special precautions for disposal <and other handling>

Any unused medicinal product or waste material should be disposed of in accordance with "Regulation on Control of Medical Waste" and "Regulation on Control of Packaging and Packaging Wastes".

## 7. MARKETING AUTHORISATION HOLDER

Name and address: BİLİM İLAÇ SAN. ve TİC. A. Ş. Kaptanpaşa Mah. Zincirlikuyu Cad. No:184; 34440 Beyoğlu-ISTANBUL-TURKEY

Phone: +90 (212) 365 15 00

Fax: +90 (212) 276 29 19

## 8. MARKETING AUTHORISATION NUMBER(S)

**Certificate No: 06763/08159/REN/2021**

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 4, 2021

## 10. DATE OF REVISION OF THE TEXT

September 2023