# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

CEFTINEX 125 mg/5 ml

Dry Powder For Oral Suspension

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle contains 125 mg/5 ml Cefdinir as active ingredient, sodium benzoate as preservative, strawberry and cream flavours as aromatic agent.

## 3. PHARMACEUTICAL FORM

Powder for oral suspension

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Ceftinex suspension is indicated for the treatment bacterial infections such as;

- Acute Bacterial Otitis Media: caused by *Haemophilus influenzae* (including beta-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis* (including beta-lactamase producing strains).
- Acute Maxillary Sinusitis: caused by *Haemophilus influenzae* (including beta-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis* (including beta-lactamase producing strains).
- Acute Bacterial Rhinosinusitis: caused by *Haemophilus influenzae* (including beta-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-sensitive strains only) and *Moraxella catarrhalis* (including beta-lactamase producing strains).
- Pharyngitis/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

Posology

The recommended dosage and duration of treatment in pediatric patients aged 6 months to 12 years of age are described in the following chart; total daily dose for all infections is 14 mg/kg up to a maximum dose of 600 mg per day. Once daily dosing for 10 days is as effective as BID dosing. Once-daily dosing have not been studied in skin infections; therefore, Ceftinex for oral suspension should be administrated twice daily in this infection. Ceftinex oral suspension may be administrated without regard to meals.

**Dosage Chart For Pediatric Patient Aged Between 6 months to 12 years of age**

| **Type of Infection Dosage Duration** | **Type of Infection Dosage Duration** | **Type of Infection Dosage Duration** |
|---|---|---|
| Acute Bacterial Otitis | 7 mg/kg per12 hour period<br>or<br>14 mg/kg single daily dose | 5 to 10 days<br><br>10 days |
| Acute Maxillary Sinusitis | 7 mg/kg per 12 hours<br>or<br>14 mg/kg single daily dose | 10 days<br><br>10 days |
| Pharyngitis/Tonsillitis | 7 mg/kg per12 hour period<br>or<br>14 mg/kg single daily dose | 5 to 10 days<br><br>10 days |
| Uncomplicated Skin Infections | 7 mg/kg per12 hour period | 10 days |

| **CEFTİNEX FOR ORAL SUSPANSION PEDIATRIC DOSAGE CHART** | |
|---|---|
| 9 kg | 2.5 mL per 12 hours or 5 mL single daily dose |
| 18 kg | 5 mL per 12 hours or 10 mL single daily dose |
| 27 kg | 7.5 mL per 12 hours or 15 mL single daily dose |
| 36 kg | 10 mL per 12 hours or 20 mL single daily dose |
| >43 kg | 12 mL per 12 hours or 24 mL single daily dose |

Pediatric patients who weigh >43 kg should receive the maximum daily dose of 600 mg.

Geriatric use: 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.

Method of administration

**Directions for Mixing Oral Suspension:** Put boiled and cooled water up to the half level of the sign on the bottle than shake well. For a homogeneous dispersal wait for 5 minutes.
Add water up to the sign level and then shake again. After mixing, the suspension can be stored 10 days at controlled room temperature.
SHAKE ORAL SUSPENSION WELL BEFORE USING.

## 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

**Pregnancy category: B**

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.

**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 suspension 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 methicillinresistant 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. The absolute bioavailability of cefdinir is 25%. It should be taken without regard to food.

Following administration of single 7mg/kg dose of cefdinir to children between 6 months- 12 years of age, the values of Cmax (µg/mL), tmax (hour) and AUC (µg. hour/mL) were determined 2.30, 2.2, 8.31, respectively and following the administration of single 14 mg/kg dose of cefdinir, they were 3.86, 1.8, 13.4, respectively.

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

and reproductive performance were not affected in rats at oral doses up to 1000 mg/kg/day (70 times the human dose on a mg/kg/day basis, 11 times on a mg/m2/day basis).

Oral doses up to 1000 mg/kg/day (70 times the human dose on a mg/kg/day basis, 11 times the mg/m2/day) in rats or 10 mg/kg/day in rabbits (0% human dose on a mg/kg/day basis) Cefdinir showed no teratogenic effect at oral doses up to 0.7 times, 0.23 times on a mg/m2/day basis. Maternal toxicity (reduced weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day, with no progeny adverse effects. Decreased body weight was observed at ≥ 100 mg/kg/day in rat fetuses and ≥ 32 mg/kg/day in rat progeny. No effects on maternal reproductive parameters, progeny survival, development, behavior or reproductive function were observed.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid anhydrous
Sodium citrate dihydrate
Sodium benzoate
Xanthan gum
Guar Gum (Guar Gallaktomannan)
Silica Colloidal Hydrate (Syloid 244 FB)
Magnesium stearate
Strawberry flavour (501098)
Cream flavour (50673)
Sucrose

### 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 below 30 oC, 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>

Cefdinir Powder for Suspension is packaged in 100 ml scaled amber colored Type III glass bottle with a measuring spoon and HDPE opaque white coloured cap 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

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## 8. MARKETING AUTHORISATION NUMBER(S)

**Certificate No: 06620/08151/REN/2021**

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

Oct 19, 2021

## 10. DATE OF REVISION OF THE TEXT

September 2023

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