

# CEPHALEXIN- cephalexin powder, for suspension

## Preferred Pharmaceuticals Inc.

-----

### HIGHLIGHTS OF PRESCRIBING INFORMATION

**These highlights do not include all the information needed to use Cephalexin for Oral Suspension safely and effectively. See full prescribing information for Cephalexin for Oral Suspension Cephalexin for Oral Suspension Initial U.S. Approval: 1971**

### ----- INDICATIONS AND USAGE -----

Cephalexin for Oral Suspension is a cephalosporin antibacterial drug indicated for the treatment of the following infections caused by susceptible isolates of designated bacteria: (1)

- Respiratory tract infection (1.1)
- Otitis media (1.2)
- Skin and skin structure infections (1.3)
- Bone infections (1.4)
- Genitourinary tract infections (1.5)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cephalexin for Oral Suspension and other antibacterial drugs, Cephalexin for Oral Suspension should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. (1.6) (1)

### ----- DOSAGE AND ADMINISTRATION -----

Adults and patients at least 15 years of age (2)	The usual dose is 250 mg every 6 hours, but a dose of 500 mg every 12 hours may be administered (2.1) (2)
Pediatric patients (over 1 year of age) (2)	<ul style="list-style-type: none"><li>• Otitis media: 75 to 100 mg/kg in equally divided doses every 6 hours (2.2)</li><li>• All other indications: 25 to 50 mg/kg given in equally divided doses (2.2)</li><li>• In severe infections: 50 to 100 mg/kg may be administered in equally divided doses (2.2)</li></ul>

- Duration of therapy ranges from 7 to 14 days depending on the infection type and severity. (2)
- Dosage adjustment is required in patients with severe and end stage renal disease (ESRD) defined as creatinine clearance below 30 mL/min. (2.3)

### ----- DOSAGE FORMS AND STRENGTHS -----

For oral suspension: 125mg/5mL and 250mg/5mL (3) (3)

### ----- CONTRAINDICATIONS -----

Patients with known hypersensitivity to cephalexin or other members of the cephalosporin class of antibacterial drugs. (4) (4)

### ----- WARNINGS AND PRECAUTIONS -----

- Serious hypersensitivity (anaphylactic) reactions: Prior to use, inquire regarding history of hypersensitivity to beta-lactam antibacterial drugs. Discontinue the drug if signs or symptoms of an allergic reaction occur and institute supportive measures. (5.1)
- Clostridium difficile-associated diarrhea (CDAD): Evaluate if diarrhea occurs. (5.2)
- Direct Coombs' Test Seroconversion: If anemia develops during or after cephalexin therapy, evaluate for drug-induced hemolytic anemia. (5.3)
- Seizure Potential: Use lower dose in patients with renal impairment. (5.4)

### ----- ADVERSE REACTIONS -----

The most common adverse reactions associated with cephalexin include diarrhea, nausea, vomiting, dyspepsia and abdominal pain. (6) (6)

**To report SUSPECTED ADVERSE REACTIONS, contact Orchid at 866-562-4590 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). (6)**

-----  
**DRUG INTERACTIONS**  
-----

- Metformin: increased metformin concentrations. Monitor for hypoglycemia. (7.1)
- Probenecid - The renal excretion of cephalexin is inhibited by probenecid. Co-administration of probenecid with cephalexin is not recommended. (7.2)
- Administration of cephalexin may result in a false-positive reaction for glucose in the urine. (7.3)

See 17 for **PATIENT COUNSELING INFORMATION**.

Revised: 4/2020

---

**FULL PRESCRIBING INFORMATION: CONTENTS\***

**1. INDICATIONS AND USAGE**

- 1.1 Respiratory Tract Infections
- 1.2 Otitis Media
- 1.3 Skin and Skin Structure Infections
- 1.4 Bone Infections
- 1.5 Genitourinary Tract Infections
- 1.6 Usage

**2. DOSAGE AND ADMINISTRATION**

- 2.1 Adults and Pediatric Patients at Least 15 years of Age
- 2.2 Pediatric Patients (over 1 year of age)
- 2.3 Dosage Adjustments in Adult and Pediatric Patients at Least 15 years of Age with Renal Impairment

**3. DOSAGE FORMS AND STRENGTHS**

**4. CONTRAINDICATIONS**

**5. WARNINGS AND PRECAUTIONS**

- 5.1 Hypersensitivity Reactions
- 5.2 *Clostridium difficile*-Associated Diarrhea
- 5.3 Direct Coombs' Test Seroconversion
- 5.4 Seizure Potential
- 5.5 Prolonged Prothrombin Time
- 5.6 Development of Drug-Resistant Bacteria

**6. ADVERSE REACTIONS**

- 6.1 Clinical Trials Experience

**7. DRUG INTERACTIONS**

- 7.1 Metformin
- 7.2 Probenecid
- 7.3 Interaction with Laboratory or Diagnostic Testing

**8. USE IN SPECIFIC POPULATIONS**

- 8.1 Pregnancy
- 8.3 Nursing Mothers
- 8.4 Pediatric Use
- 8.5 Geriatric Use
- 8.6 Renal Impairment

**10. OVERDOSAGE**

**11. DESCRIPTION**

**12. CLINICAL PHARMACOLOGY**

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics
- 12.4 Microbiology

**13. NONCLINICAL TOXICOLOGY**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

## **16. HOW SUPPLIED/STORAGE AND HANDLING**

## **17. PATIENT COUNSELING INFORMATION**

\* Sections or subsections omitted from the full prescribing information are not listed.

---

## **FULL PRESCRIBING INFORMATION**

### **1. INDICATIONS AND USAGE**

#### **1.1 Respiratory Tract Infections**

Cephalexin for Oral Suspension is indicated for the treatment of respiratory tract infections caused by susceptible isolates of *Streptococcus pneumoniae* and *Streptococcus pyogenes*.

#### **1.2 Otitis Media**

Cephalexin for Oral Suspension is indicated for the treatment of otitis media caused by susceptible isolates of *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Moraxella catarrhalis*.

#### **1.3 Skin and Skin Structure Infections**

Cephalexin for Oral Suspension is indicated for the treatment of skin and skin structure infections caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* and *Streptococcus pyogenes*.

#### **1.4 Bone Infections**

Cephalexin for Oral Suspension is indicated for the treatment of bone infections caused by susceptible isolates of *Staphylococcus aureus* and *Proteus mirabilis*.

#### **1.5 Genitourinary Tract Infections**

Cephalexin for Oral Suspension is indicated for the treatment of genitourinary tract infections, including acute prostatitis, caused by susceptible isolates of *Escherichia coli*, *Proteus mirabilis*, and *Klebsiella pneumoniae*.

#### **1.6 Usage**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cephalexin for Oral Suspension and other antibacterial drugs, Cephalexin for Oral Suspension should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information is available, this information should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

### **2. DOSAGE AND ADMINISTRATION**

#### **2.1 Adults and Pediatric Patients at Least 15 years of Age**

The usual dose of oral cephalexin is 250 mg every 6 hours, but a dose of 500 mg every 12 hours may be administered. Treatment is administered for 7 to 14 days.

For more severe infections larger doses of oral cephalexin may be needed, up to 4 grams daily in two

to four equally divided doses.

## 2.2 Pediatric Patients (over 1 year of age)

The recommended total daily dose of oral cephalexin for pediatric patients is 25 to 50 mg/kg given in equally divided doses for 7 to 14 days. In the treatment of -hemolytic streptococcal infections, duration of at least 10 days is recommended. In severe infections, a total daily dose of 50 to 100 mg/kg may be administered in equally divided doses.

For the treatment of otitis media, the recommended daily dose is 75 to 100 mg/kg given in equally divided doses.

### Cephalexin for Oral Suspension

<u>Weight</u>	<u>125mg/5mL</u>	<u>250mg/5mL</u>
10 kg (22 lb)	½ to 1 tsp q.i.d.	¼ to ½ tsp q.i.d.
20 kg (44 lb)	1 to 2 tsp q.i.d.	½ to 1 tsp q.i.d.
40 kg (88 lb)	2 to 4 tsp q.i.d.	1 to 2 tsp q.i.d.
	Or	
<u>Weight</u>	<u>125mg/5mL</u>	<u>250mg/5mL</u>
10 kg (22 lb)	1 to 2 tsp b.i.d.	½ to 1 tsp b.i.d.
20 kg (44 lb)	2 to 4 tsp b.i.d.	1 to 2 tsp b.i.d.
40 kg (88 lb)	4 to 8 tsp b.i.d.	2 to 4 tsp b.i.d.

#### Directions for Mixing

**125 mg per 5 mL (100 mL when mixed):** Prepare suspension time at dispensing. Add to the bottle a total of 71 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate equivalent to 125 mg cephalexin in each 5 mL (teaspoonful).

**125 mg per 5 mL (200 mL when mixed):** Prepare suspension time at dispensing. Add to the bottle a total of 140 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate equivalent to 125 mg cephalexin in each 5 mL (teaspoonful).

**250 mg per 5 mL (100 mL when mixed):** Prepare suspension time at dispensing. Add to the bottle a total of 71 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate equivalent to 250 mg cephalexin in each 5 mL (teaspoonful).

**250 mg per 5 mL (200 mL when mixed):** Prepare suspension time at dispensing. Add to the bottle a total of 140 mL of water. For ease in preparation, tap bottle to loosen powder, add the water in 2 portions, shaking well after each addition. The resulting suspension will contain cephalexin monohydrate equivalent to 250 mg cephalexin in each 5 mL (teaspoonful).

\*After mixing, store in refrigerator. May be kept for 14 days without significant loss of potency.

## 2.3 Dosage Adjustments in Adult and Pediatric Patients at Least 15 years of Age with Renal Impairment

Administer the following dosing regimens for cephalexin to patients with renal impairment [see *Warnings and Precautions (5.4)* and *Use in Specific Populations (8.6)*].

**Table 1. Recommended Dose Regimen for Patients with Renal Impairment**

<b>Renal function</b>	<b>Dose regimen recommendation</b>
-----------------------	------------------------------------

Creatinine clearance $\geq$ 60 mL/min	No dose adjustment
Creatinine clearance 30 to 59 mL/min	No dose adjustment; maximum daily dose should not exceed 1g
Creatinine clearance 15 to 29 mL/min	250 mg, every 8 hours or every 12 hours
Creatinine clearance 5 to 14 mL/min not yet on dialysis*	250 mg, every 24 hours
Creatinine clearance 1 to 4 mL/min not yet on dialysis*	250 mg, every 48 hours or every 60 hours

\* There is insufficient information to make dose adjustment recommendations in patients on hemodialysis.

### 3. DOSAGE FORMS AND STRENGTHS

Cephalexin for Oral Suspension, USP  
125 mg/5mL and 250 mg/5mL

### 4. CONTRAINDICATIONS

Cephalexin is contraindicated in patients with known hypersensitivity to cephalexin or other members of the cephalosporin class of antibacterial drugs.

### 5. WARNINGS AND PRECAUTIONS

#### 5.1 Hypersensitivity Reactions

Allergic reactions in the form of rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis have been reported with the use of cephalexin. Before therapy with cephalexin is instituted, inquire whether the patient has a history of hypersensitivity reactions to cephalexin, cephalosporins, penicillins, or other drugs. Cross-hypersensitivity among beta-lactam antibacterial drugs may occur in up to 10% of patients with a history of penicillin allergy.

If an allergic reaction to cephalexin occurs, discontinue the drug and institute appropriate treatment.

#### 5.2 *Clostridium difficile*-Associated Diarrhea

*Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including cephalexin, 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*.

*C. 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.

#### 5.3 Direct Coombs' Test Seroconversion

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibacterial drugs including cephalexin. Acute intravascular hemolysis induced by cephalexin therapy has been

reported. If anemia develops during or after cephalexin therapy, perform a diagnostic work-up for drug-induced hemolytic anemia, discontinue cephalexin and institute appropriate therapy.

#### **5.4 Seizure Potential**

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced. If seizures occur, discontinue cephalexin. Anticonvulsant therapy can be given if clinically indicated.

#### **5.5 Prolonged Prothrombin Time**

Cephalosporins may be associated with prolonged prothrombin time. Those at risk include patients with renal or hepatic impairment, or poor nutritional state, as well as patients receiving a protracted course of antibacterial therapy, and patients receiving anticoagulant therapy. Monitor prothrombin time in patients at risk and manage as indicated.

#### **5.6 Development of Drug-Resistant Bacteria**

Prescribing cephalexin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Prolonged use of cephalexin may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

### **6. ADVERSE REACTIONS**

#### **6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice

In clinical trials, the most frequent adverse reaction was diarrhea. Nausea and vomiting, dyspepsia, gastritis, and abdominal pain have also occurred. As with penicillins and other cephalosporins, transient hepatitis and cholestatic jaundice have been reported.

Other reactions have included hypersensitivity reactions, genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis, and joint disorder. Reversible interstitial nephritis has been reported. Eosinophilia, neutropenia, thrombocytopenia, hemolytic anemia, and slight elevations in aspartate transaminase (AST) and alanine transaminase (ALT) have been reported.

In addition to the adverse reactions listed above that have been observed in patients treated with cephalexin, the following adverse reactions and other altered laboratory tests have been reported for cephalosporin class antibacterial drugs:

*Other Adverse Reactions:* Fever, colitis, aplastic anemia, hemorrhage, renal dysfunction, and toxic nephropathy.

*Altered Laboratory Tests:* Prolonged prothrombin time, increased blood urea nitrogen (BUN), increased creatinine, elevated alkaline phosphatase, elevated bilirubin, elevated lactate dehydrogenase (LDH), pancytopenia, leukopenia, and agranulocytosis.

### **7. DRUG INTERACTIONS**

#### **7.1 Metformin**

Administration of cephalexin with metformin results in increased plasma metformin concentrations and

decreased renal clearance of metformin.

Careful patient monitoring and dose adjustment of metformin is recommended in patients concomitantly taking cephalexin and metformin [see *Clinical Pharmacology* (12.3)].

## **7.2 Probenecid**

The renal excretion of cephalexin is inhibited by probenecid. Co-administration of probenecid with cephalexin is not recommended.

## **7.3 Interaction with Laboratory or Diagnostic Testing**

A false-positive reaction may occur when testing for the presence of glucose in the urine using Benedict's solution or Fehling's solution.

# **8. USE IN SPECIFIC POPULATIONS**

## **8.1 Pregnancy**

Pregnancy Category B

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Reproduction studies have been performed on mice and rats using oral doses of cephalexin monohydrate 0.6 and 1.5 times the maximum daily human dose (66 mg/kg/day) based upon body surface area basis, and have revealed no evidence of impaired fertility or harm to the fetus.

## **8.3 Nursing Mothers**

Cephalexin is excreted in human milk. Caution should be exercised when cephalexin is administered to a nursing woman.

## **8.4 Pediatric Use**

The safety and effectiveness of cephalexin in pediatric patients was established in clinical trials for the dosages described in the dosage and administration section [see *Dosage and Administration* (2.2)].

## **8.5 Geriatric Use**

Of the 701 subjects in 3 published clinical studies of cephalexin, 433 (62%) were 65 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

This drug is substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection [see *Warnings and Precautions* (5.4)].

## **8.6 Renal Impairment**

Cephalexin should be administered with caution in the presence of impaired renal function (creatinine clearance < 30 mL/min, with or without dialysis). Under such conditions, careful clinical observation and laboratory studies renal function monitoring should be conducted because safe dosage may be lower than that usually recommended [see *Dosage and Administration* (2.3)].

# **10. OVERDOSAGE**

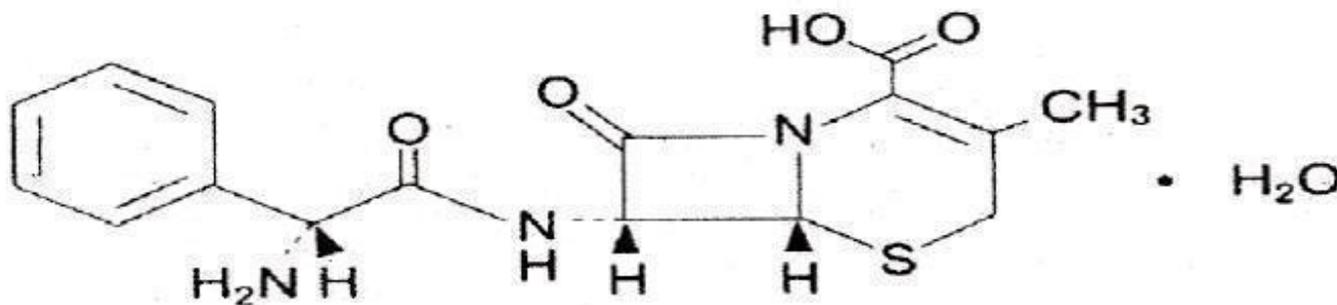
Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhea, and hematuria. In the event of an overdose, institute general supportive measures.

Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of cephalexin.

## 11. DESCRIPTION

Cephalexin for Oral Suspension, USP is a semisynthetic cephalosporin antibacterial drug intended for oral administration. It is 7-(D- $\alpha$ -Amino- $\alpha$ -phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid monohydrate. Cephalexin has the molecular formula  $C_{16}H_{17}N_3O_4S \cdot H_2O$  and the molecular weight is 365.41.

Cephalexin has the following structural formula:



Inactive Ingredients: SUSPENSION: The suspensions also contain the following inactive ingredients: colloidal silicon dioxide, FD&C Yellow No.6, tutti-frutti flavor, orange flavor, sodium lauryl sulphate, sucrose and xanthan gum.

## 12. CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Cephalexin is a cephalosporin antibacterial drug [see *Microbiology* (12.4)].

### 12.3 Pharmacokinetics

#### Absorption:

Cephalexin is acid stable and may be given without regard to meals. Following doses of 250 mg, 500 mg, and 1 g, average peak serum levels of approximately 9, 18, and 32 mcg/mL, respectively, were obtained at 1 hour. Serum levels were detectable 6 hours after administration (at a level of detection of 0.2 mcg/mL).

#### Distribution:

Cephalexin is approximately 10% to 15% bound to plasma proteins.

#### Excretion:

Cephalexin is excreted in the urine by glomerular filtration and tubular secretion. Studies showed that over 90% of the drug was excreted unchanged in the urine within 8 hours. During this period, peak urine concentrations following the 250 mg, 500 mg, and 1 g doses were approximately 1000, 2200, and 5000 mcg/mL respectively.

#### Drug Interactions:

In healthy subjects given single 500 mg doses of cephalexin and metformin, plasma metformin mean  $C_{max}$  and AUC increased by an average of 34% and 24%, respectively, and metformin mean renal clearance decreased by 14%. No information is available about the interaction of cephalexin and metformin following multiple doses of either drug.

## 12.4 Microbiology

### Mechanism of Action

Cephalexin is a bactericidal agent that acts by the inhibition of bacterial cell-wall synthesis.

### Resistance

Methicillin-resistant staphylococci and most isolates of enterococci are resistant to cephalexin. Cephalexin is not active against most isolates of *Enterobacter spp.*, *Morganella morganii*, and *Proteus vulgaris*. Cephalexin has no activity against *Pseudomonas spp.*, or *Acinetobacter calcoaceticus*. Penicillin-resistant *Streptococcus pneumoniae* is usually cross-resistant to beta-lactam antibacterial drugs.

### Antimicrobial Activity

Cephalexin has been shown to be active against most isolates of the following bacteria both *in vitro* and in clinical infections [see *Indications and Usage (1)*].

#### Gram-positive bacteria

*Staphylococcus aureus* (methicillin-susceptible isolates only)

*Streptococcus pneumoniae* (penicillin-susceptible isolates)

*Streptococcus pyogenes*

#### Gram-negative bacteria

*Escherichia coli*

*Haemophilus influenzae*

*Klebsiella pneumoniae*

*Moraxella catarrhalis*

*Proteus mirabilis*

#### Susceptibility Testing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/STIC>.

## 13. NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Lifetime studies in animals have not been performed to evaluate the carcinogenic potential of cephalexin. Tests to determine the mutagenic potential of cephalexin have not been performed. In male and female rats, fertility and reproductive performance were not affected by cephalexin oral doses up to 1.5 times the highest recommended human dose based upon body surface area.

## 16. HOW SUPPLIED/STORAGE AND HANDLING

Cephalexin for Oral Suspension, USP, is supplied as follows:

The 250 mg/5 mL oral suspension is available as follows

100 - mL Bottles NDC 68788-8986-1

200 - mL Bottles NDC 68788-8986-2

Directions for mixing are included on the label.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Shake well before using. Keep tightly closed.

After mixing store in a refrigerator. May be kept for 14 days without significant loss of potency.

## 17. PATIENT COUNSELING INFORMATION

- Advise patients that allergic reactions, including serious allergic reactions, could occur and that serious reactions require immediate treatment. Ask the patient about any previous hypersensitivity reactions to cephalexin, other beta-lactams (including cephalosporins) or other allergens (5.1)
- Advise patients that diarrhea is a common problem caused by antibacterial drugs and usually resolves when the drug is discontinued. Sometimes, frequent watery or bloody diarrhea may occur and may be a sign of a more serious intestinal infection. If severe watery or bloody diarrhea develops, advise patients to contact their healthcare provider.
- Counsel patients that antibacterial drugs including cephalexin, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cephalexin is prescribed to treat a bacterial infection, tell patients 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 (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by cephalexin or other antibacterial drugs in the future.

Distributed by: OrchidPharma, Inc.  
Princeton, NJ 08540, USA

Manufactured for: Orchid Healthcare  
(A Division of Orchid Pharma Ltd.)  
Irungattukottai – 602 117, India

Revised: 2/2020

**Relabeled By: Preferred Pharmaceuticals Inc.**

OrchidPharma

NDC 68788-8986

**Cephalexin**

**for Oral**

**Suspension, USP**

**250 mg/5 mL**

**100 mL (When Mixed)**

**Rx only**

**Relabeled By: Preferred Pharmaceuticals Inc.**

<p><b>Cephalexin for Oral Suspension, USP 250mg/5mL</b></p> <p>Generic for Keflex When reconstituted each teaspoonful (5mL) contains: cephalexin monohydrate eq. to 250 mg anhydrous cephalexin</p> <p><b>Pkg Size:</b>    <b>Exp Date:</b> Lot#: _____ Batch#: _____ Ins: _____ Mfg: OrchidPharma, Inc.; Princeton, NJ Prod#: _____</p> <p><b>Warning</b> Prior to mixing, store at 20°-25°C (68°-77°F) See USP Controlled Room Temperature. Keep this and all medication out of the reach of children. Shake well before using. Store in a refrigerator, may be kept for 14 days without significant loss of potency. Keep tightly closed. Discard unused portion after 14 days.</p>		<p>Cephalexin for Oral Suspension, USP 250mg/5mL Qty: Ins: _____ Lot#: Bat#: _____</p> <p>Prod# (NDC): _____</p> <p>Cephalexin for Oral Suspension, USP 250mg/5mL Qty: Ins: _____ Lot#: Bat#: _____ Prod# (NDC): _____</p> <p>Cephalexin for Oral Suspension, USP 250mg/5mL Insurance NDC: _____ Lot#: Bat#: _____</p> <p>Cephalexin for Oral Suspension, USP 250mg/5mL Qty: Ins: _____ Lot#: Bat#: _____ Prod# (NDC): _____</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
<p><b>Directions English</b></p> <p>Take _____ teaspoonful(s) every _____ hours.</p>		<p><b>Instrucciones Espanol:</b></p> <p>Toma _____ cucharrita(s) cada _____ horas</p>	

# CEPHALEXIN

cephalexin powder, for suspension

## Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68788-8986(NDC:42043-143)
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEPHALEXIN (UNII: OBN7UDS42Y) (CEPHALEXIN ANHYDROUS - UNII:5SFF1W6677)	CEPHALEXIN ANHYDROUS	250 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	TUTTI FRUTTI, ORANGE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8986-1	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2016	
2	NDC:68788-8986-2	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065326	02/01/2016	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

**Establishment**

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		79 1119022	RELABEL(68788-8986)

Revised: 4/2020

Preferred Pharmaceuticals Inc.