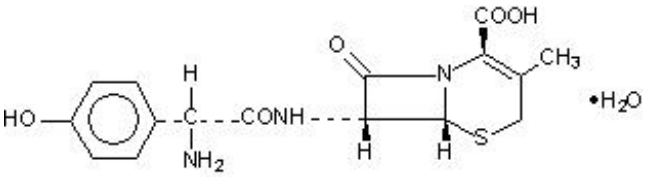
CEFADROXIL - cefadroxil powder, for suspension
Rising Pharma Holdings, Inc.

Cefadroxil for Oral Suspension, USP
Rx only

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefadroxil and other antibacterial drugs, cefadroxil should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Cefadroxil monohydrate, USP is a semisynthetic cephalosporin antibiotic intended for oral administration. It is a white to yellowish-white crystalline powder. It is soluble in water and it is acid-stable. It is chemically designated as 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[amino(4-hydroxyphenyl)acetyl]amino]-3-methyl-8-oxo-, monohydrate, [6R-[6α,7β(R*)]]-. It has the formula $C_{16}H_{17}N_3O_5S \cdot H_2O$ and the molecular weight of 381.40. It has the following structural formula:



Cefadroxil for oral suspension USP, after reconstitution, contains cefadroxil monohydrate equivalent to 250 mg or 500 mg cefadroxil base per 5 mL. In addition, cefadroxil for oral suspension also contains the following inactive ingredients: FD&C Yellow No. 6 Aluminum lake, polysorbate 80, sodium benzoate, sucrose, xanthan gum, orange flavor and pineapple flavor. The orange flavor and pineapple flavor contains sulfur dioxide.

CLINICAL PHARMACOLOGY

Cefadroxil is rapidly absorbed after oral administration. Following single doses of 500 mg and 1000 mg, average peak serum concentrations were approximately 16 and 28 mcg/mL, respectively. Measurable levels were present 12 hours after administration. Over 90% of the drug is excreted unchanged in the urine within 24 hours. Peak urine concentrations are approximately 1800 mcg/mL during the period following a single 500

mg oral dose. Increases in dosage generally produce a proportionate increase in cefadroxil monohydrate urinary concentration. The urine antibiotic concentration, following a 1 g dose, was maintained well above the MIC of susceptible urinary pathogens for 20 to 22 hours.

Microbiology

In vitro tests demonstrate that the cephalosporins are bactericidal because of their inhibition of cell-wall synthesis. Cefadroxil has been shown to be active against the following organisms both *in vitro* and in clinical infections (see **INDICATIONS AND USAGE**):

Beta-hemolytic streptococci
Staphylococci, including penicillinase-producing strains
Streptococcus (Diplococcus) pneumoniae
Escherichia coli
Proteus mirabilis
Klebsiella species
Moraxella (Branhamella) catarrhalis

Note: Most strains of *Enterococcus faecalis* (formerly *Streptococcus faecalis*) and *Enterococcus faecium* (formerly *Streptococcus faecium*) are resistant to cefadroxil monohydrate. It is not active against most strains of *Enterobacter* species, *Morganella morganii* (formerly *Proteus morganii*), and *P. vulgaris*. It has no activity against *Pseudomonas* species and *Acinetobacter calcoaceticus* (formerly *Mima* and *Herellea* species).

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.

INDICATIONS AND USAGE

Cefadroxil is indicated for the treatment of patients with infection caused by susceptible strains of the designated organisms in the following diseases:

Urinary tract infections caused by *E. coli, P. mirabilis,* and *Klebsiella* species.

Skin and skin structure infections caused by staphylococci and/or streptococci.

Pharyngitis and/or tonsillitis caused by *Streptococcus pyogenes* (Group A beta-hemolytic streptococci).

Note: Only penicillin by the intramuscular route of administration has been shown to be effective in the prophylaxis of rheumatic fever. Cefadroxil is generally effective in the

eradication of streptococci from the oropharynx. However, data establishing the efficacy of cefadroxil for the prophylaxis of subsequent rheumatic fever are not available.

Note: Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

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

CONTRAINDICATIONS

Cefadroxil is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

WARNINGS

BEFORE THERAPY WITH CEFADROXIL IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFADROXIL, CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-SENSITIVITY 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 CEFADROXIL OCCURS, DISCONTINUE THE DRUG. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

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

Cefadroxil for oral suspension contains sulfur dioxide, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

PRECAUTIONS

General

Cefadroxil should be used with caution in the presence of markedly impaired renal function (creatinine clearance rate of less than 50 mL/min/1.73 m^2). (See **DOSAGE AND ADMINISTRATION**.) In patients with known or suspected renal impairment, careful clinical observation and appropriate laboratory studies should be made prior to and during therapy.

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

Prolonged use of cefadroxil 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.

Cefadroxil should be prescribed with caution in individuals with history of gastrointestinal disease particularly colitis.

Information for Patients

Patients should be counseled that antibacterial drugs including cefadroxil should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cefadroxil is prescribed to treat a bacterial infection, patients 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 (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by cefadroxil or other antibacterial drugs in the future.

Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, 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 antibiotic. If this occurs, patients should contact their physician as soon as possible.

Drug/Laboratory Test Interactions

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies have been performed to determine carcinogenic potential. No genetic toxicity tests have been performed.

Pregnancy

Pregnancy Category B

Reproduction studies have been performed in mice and rats at doses up to 11 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cefadroxil monohydrate. There are, however, 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.

Labor and Delivery

Cefadroxil has not been studied for use during labor and delivery. Treatment should only be given if clearly needed.

Nursing Mothers

Caution should be exercised when cefadroxil monohydrate is administered to a nursing mother.

Pediatric Use

(See **DOSAGE AND ADMINISTRATION**.)

Geriatric Use

Of approximately 650 patients who received cefadroxil for the treatment of urinary tract infections in three clinical trials, 28% were 60 years and older, while 16% were 70 years and older. Of approximately 1000 patients who received cefadroxil for the treatment of skin and skin structure infection in 14 clinical trials, 12% were 60 years and older while 4% were 70 years and over. No overall differences in safety were observed between the elderly patients in these studies and younger patients. Clinical studies of cefadroxil for the treatment of pharyngitis or tonsillitis did not include sufficient numbers of patients 65 years and older to determine whether they respond differently from younger patients. Other reported clinical experience with cefadroxil has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Cefadroxil is substantially excreted by the kidney, and dosage adjustment is indicated for patients with renal impairment (see **DOSAGE AND ADMINISTRATION: Renal Impairment**). Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Gastrointestinal

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see **WARNINGS**). Dyspepsia, nausea and vomiting have been reported rarely. Diarrhea has also occurred.

Hypersensitivity

Allergies (in the form of rash, urticaria, angioedema, and pruritus) have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other

Other reactions have included hepatic dysfunction including cholestasis and elevations in serum transaminase, genital pruritus, genital moniliasis, vaginitis, moderate transient neutropenia, fever. Agranulocytosis, thrombocytopenia, idiosyncratic hepatic failure, erythema multiforme, Stevens-Johnson syndrome, serum sickness, and arthralgia have been rarely reported.

In addition to the adverse reactions listed above which have been observed in patients

treated with cefadroxil, the following adverse reactions and altered laboratory tests have been reported for cephalosporin-class antibiotics:

Toxic epidermal necrolysis, abdominal pain, superinfection, renal dysfunction, toxic nephropathy, aplastic anemia, hemolytic anemia, hemorrhage, prolonged prothrombin time, positive Coombs' test, increased BUN, increased creatinine, elevated alkaline phosphatase, elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT), elevated bilirubin, elevated LDH, eosinophilia, pancytopenia, neutropenia.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment, when the dosage was not reduced (see **DOSAGE AND ADMINISTRATION** and **OVERDOSAGE**). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE

A study of children under six years of age suggested that ingestion of less than 250 mg/kg of cephalosporins is not associated with significant outcomes. No action is required other than general support and observation. For amounts greater than 250 mg/kg, induce gastric emptying.

In five anuric patients, it was demonstrated that an average of 63% of a 1 g oral dose is extracted from the body during a 6 to 8 hour hemodialysis session.

DOSAGE AND ADMINISTRATION

Cefadroxil is acid-stable and may be administered orally without regard to meals. Administration with food may be helpful in diminishing potential gastrointestinal complaints occasionally associated with oral cephalosporin therapy.

Adults

Urinary Tract Infections: For uncomplicated lower urinary tract infections (i.e., cystitis) the usual dosage is 1 or 2 g per day in a single (q.d.) or divided doses (b.i.d.).

For all other urinary tract infections the usual dosage is 2 g per day in divided doses (b.i.d.).

Skin and Skin Structure Infections: For skin and skin structure infections the usual dosage is 1 g per day in single (q.d.) or divided doses (b.i.d.).

Pharyngitis and Tonsillitis: Treatment of group A beta-hemolytic streptococcal pharyngitis

and tonsillitis—1 g per day in single (q.d.) or divided doses (b.i.d.) for 10 days.

Children

For urinary tract infections, the recommended daily dosage for children is 30 mg/kg/day in divided doses every 12 hours. For pharyngitis, tonsillitis, and impetigo, the recommended daily dosage for children is 30 mg/kg/day in a single dose or in equally divided doses every 12 hours. For other skin and skin structure infections, the recommended daily dosage is 30 mg/kg/day in equally divided doses every 12 hours. In the treatment of beta-hemolytic streptococcal infections, a therapeutic dosage of cefadroxil should be administered for at least 10 days.

See chart for total daily dosage for children.

DAILY DOSAGE OF CEFADROXIL SUSPENSION			
Child's Weight			
lbs	**kg**	**250 mg/5 mL**	**500 mg/5 mL**
10	4.5	½ tsp	
20	9.1	1 tsp	
30	13.6	1½ tsp	
40	18.2	2 tsp	1 tsp
50	22.7	2½ tsp	1¼ tsp
60	27.3	3 tsp	1½ tsp
70 & above	31.8+	—	2 tsp

Renal Impairment

In patients with renal impairment, the dosage of cefadroxil monohydrate should be adjusted according to creatinine clearance rates to prevent drug accumulation. The following schedule is suggested. In adults, the initial dose is 1000 mg of cefadroxil and the maintenance dose (based on the creatinine clearance rate [mL/min/1.73 m^2]) is 500 mg at the time intervals listed below.

Creatinine Clearances	**Dosage Interval**
0 to 10 mL/min	36 hours
10 to 25 mL/min	24 hours
25 to 50 mL/min	12 hours

Patients with creatinine clearance rates over 50 mL/min may be treated as if they were patients having normal renal function.

Reconstitution Directions for Oral Suspension	
Bottle Size	Reconstitution Directions
100 mL	Suspend in a total of 60 mL water. Method: Tap bottle lightly to loosen powder. Add 60 mL of water in two portions. Shake well after each addition.
75 mL	Suspend in a total of 45 mL water. Method: Tap bottle lightly to loosen powder. Add 45 mL of water in two portions. Shake well after each addition.
50 mL	Suspend in a total of 30 mL water. Method: Tap bottle lightly to loosen powder. Add 30 mL of water in two portions. Shake well after each addition.
After reconstitution, store in refrigerator. Shake well before using. Keep container tightly closed. Discard unused portion after 14 days.	

HOW SUPPLIED

Cefadroxil for Oral Suspension, USP is an off white to light orange colored granular powder which after reconstitution is orange colored and is orange-pineapple flavored, and is supplied as follows:

250 mg/5 mL

50 mL Bottle	NDC 57237-097-50
100 mL Bottle	NDC 57237-097-01

500 mg/5 mL

75 mL Bottle	NDC 57237-098-75
100 mL Bottle	NDC 57237-098-01

Prior to reconstitution: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

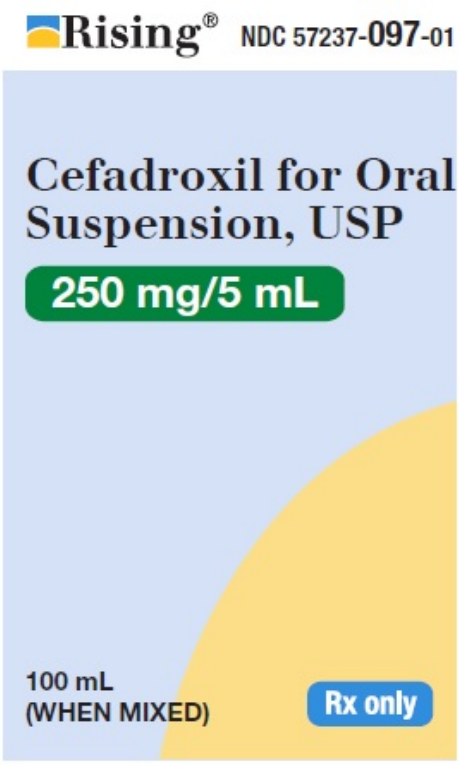
Code: TS/DRUGS/78/1996

Revised: 10/2018

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 250 mg/5 mL (100 mL WHEN MIXED)

Rising® NDC 57237-097-01

Cefadroxil for Oral Suspension, USP
250 mg/5 mL
100 mL Rx only
(WHEN MIXED)



TO PREPARE SUSPENSION: Tap bottle lightly to loosen powder. Add 60 mL of water in two portions. Shake well after each addition. After mixing, store in refrigerator. When mixed as directed, each 5 mL (approximately one teaspoonful) will contain: cefadroxil monohydrate equivalent to 250 mg cefadroxil USP.

USUAL DOSAGE: See accompanying prescribing information.

Allergy Information: Contains sulfur dioxide.

Shake well before using.

Store in a refrigerator.

Keep container tightly closed. Discard unused portion after 14 days.

Keep this and all drugs out of the reach of children.

Do not use if the safety seal under cap is broken or missing.

Store dry powder at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

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Made in India

Code: TS/DRUGS/78/1996

Revised: 10/2017

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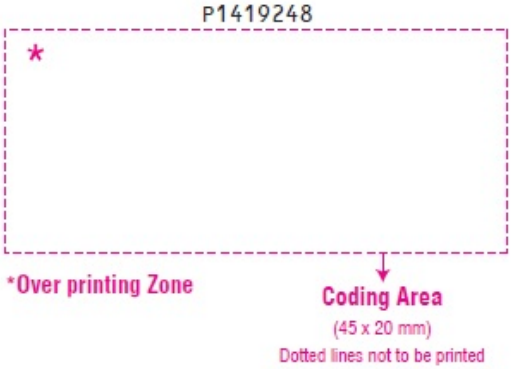
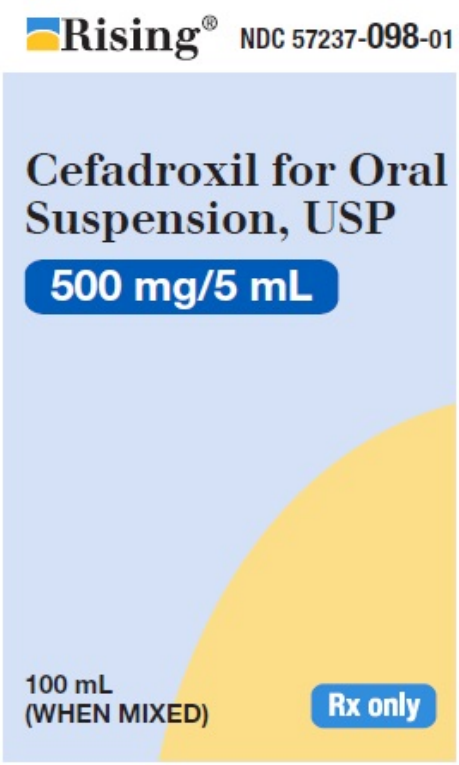


PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 500 mg/5 mL (100 mL WHEN MIXED)

Rising® NDC 57237-098-01

Cefadroxil for Oral Suspension, USP
500 mg/5 mL
100 mL Rx only

(WHEN MIXED)



TO PREPARE SUSPENSION: Tap bottle lightly to loosen powder. Add 60 mL of water in two portions. Shake well after each addition. After mixing, store in refrigerator. When mixed as directed, each 5 mL (approximately one teaspoonful) will contain: cefadroxil monohydrate equivalent to 500 mg cefadroxil USP.

USUAL DOSAGE: See accompanying prescribing information.

Allergy Information: Contains sulfur dioxide.

Shake well before using.

Store in a refrigerator.

Keep container tightly closed. Discard unused portion after 14 days.

Keep this and all drugs out of the reach of children.

Do not use if the safety seal under cap is broken or missing.

Store dry powder at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

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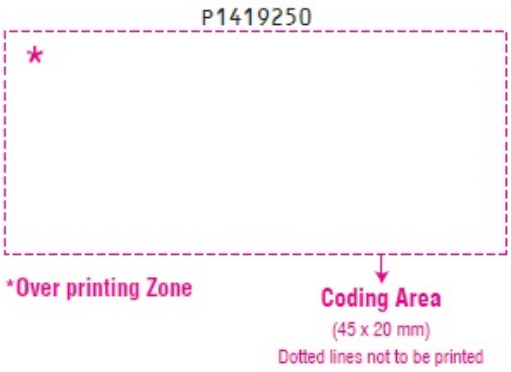

CEFADROXIL

cefadroxil powder, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57237-097
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEFADROXIL (UNII: 280111G160) (CEFADROXIL ANHYDROUS - UNII:Q525PA8JJB)	CEFADROXIL ANHYDROUS	250 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SULFUR DIOXIDE (UNII: 0UZA3422Q4)	

Product Characteristics			
Color	ORANGE (off white to light orange)	**Score**	
Shape		**Size**	
Flavor	ORANGE, PINEAPPLE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57237-097-50	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2013	
2	NDC:57237-097-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065349	04/25/2013	

CEFADROXIL

cefadroxil powder, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:57237-098
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEFADROXIL (UNII: 280111G160) (CEFADROXIL ANHYDROUS - UNII:Q525PA8JJB)	CEFADROXIL ANHYDROUS	500 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SULFUR DIOXIDE (UNII: 0UZA3422Q4)	

Product Characteristics			
Color	ORANGE (off white to light orange)	**Score**	
Shape		**Size**	
Flavor	ORANGE, PINEAPPLE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-098-75	75 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2013	
2	NDC:57237-098-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065349	04/25/2013	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917639	ANALYSIS(57237-097, 57237-098) , MANUFACTURE(57237-097, 57237-098)

Revised: 2/2024 Rising Pharma Holdings, Inc.