

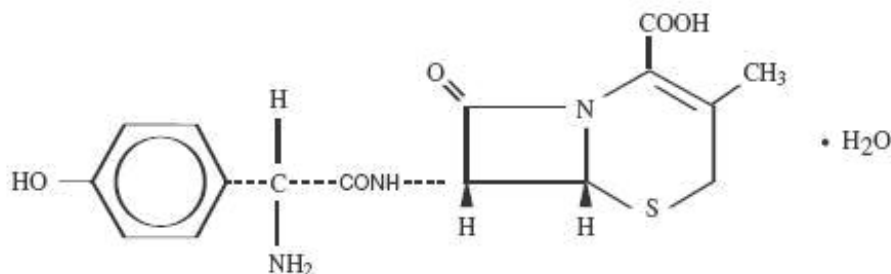
**CEFADROXIL- cefadroxil tablet, film coated**  
**Hikma Pharmaceuticals USA Inc.**

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**Cefadroxil Tablets, USP**  
**Rev. 11/2020**  
**Rx Only**

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

**DESCRIPTION**

Cefadroxil Tablets, USP is a semisynthetic cephalosporin antibiotic intended for oral administration. It is a white to off-white crystalline powder. It is soluble in water and it is acid-stable. It is chemically designated as (6 *R*,7*R*)-7-[(*R*)-2-amino-2-(*p*-hydroxyphenyl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid monohydrate. It has the following structural formula:



$C_{16}H_{17}N_3O_5 \cdot H_2O$  M.W. 381.40

Cefadroxil oral tablets available in 1 g strength contain the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol-partially hydrolyzed, talc, and titanium 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 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) pneumonia*

*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. 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 Tests

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 Tablets, USP are 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 Tablets, USP and other antibacterial drugs, Cefadroxil Tablets, USP 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 epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

### CONTRAINDICATIONS

Cefadroxil tablets are 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.

## **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<sup>2</sup>). (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 tablets 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 tablets should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When cefadroxil tablets are 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 tablets 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**

Teratogenic Effects

#### *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 1,000 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.

**To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-233-2001, or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

## **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 tablets are 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 tablets should be administered for at least 10 days.

### **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 tablets and the maintenance dose (based on the creatinine clearance rate [mL/min/1.73 m<sup>2</sup>]) is 500 mg at the time intervals listed below.

<b>Creatinine Clearances</b>	<b>Dosage Interval</b>
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.

## **HOW SUPPLIED**

Cefadroxil Tablets USP, 1 g are available as white to off-white capsule shaped, bisected film coated tablets, imprinted “WW” on the left side of the break-line and “948” on the right side.

Cefadroxil Tablets USP, are supplied as follows:

Bottle of 50

Bottle of 100

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

Dispense in a tight container as defined in the USP using a child-resistant closure.

### **Distributed by:**

**West-Ward Pharmaceuticals Corp.**

Eatontown, NJ 07724 USA

### **Manufactured by:**

**Jazeera Pharmaceutical Industries (JPI)**

Al- Kharj Road

P. O. Box 106229

Riyadh 11666

Saudi Arabia

### **An Affiliate of:**

**Hikma Pharmaceuticals LLC**

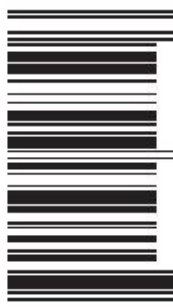
P.O. Box 182400

Amman 11118

Jordan

Revised November 2020

NDC 0143-9948-50  
CEFADROXIL TABLETS, USP  
1 gram  
Rx Only  
50 FILM COATED TABLETS

<b>DESCRIPTION:</b> Each film coated tablet contains cefadroxil monohydrate equivalent to 1 g of cefadroxil. See insert for indications and dosage schedule. <b>KEEP TIGHTLY CLOSED.</b> Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight container as defined in the USP using a child-resistant closure.	NDC 0143-9948-50	<b>KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.</b>	<b>3 0143-9948-50 6</b>	unvarnished area
	<b>CEFADROXIL TABLETS, USP</b>			
L-4	Rx Only	<b>50 FILM COATED TABLETS</b>		Exp. Date: Batch no.:
	<b>Distributed by</b> <b>West-ward Pharmaceutical Corp.</b> Eatontown, NJ 07724		<small>Manufactured by: Jazeera Pharmaceutical Industries P.O. Box 106229, Riyadh 11666 - Saudi Arabia An Affiliate of: HIKMA Pharmaceuticals P.O. Box 182400, Amman 11118 - Jordan</small>	
			<small>Rev. 11/2009 E</small>	

## CEFADROXIL

cefadroxil tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0143-9948
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CEFADROXIL (UNII: 280111G160) (CEFADROXIL ANHYDROUS - UNII:Q525PA8JJB)	CEFADROXIL ANHYDROUS	1 g

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	WW;948
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0143-9948-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2006	
2	NDC:0143-9948-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2006	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065260	03/30/2006	

**Labeler** - Hikma Pharmaceuticals USA Inc. (001230762)

Revised: 11/2020

Hikma Pharmaceuticals USA Inc.