CEFADUR Tablet (Cefadroxil)

Composition

CEFADUR-500
Each Film-coated tablet contains
Cefadroxil IP equivalent to
Cefadroxil anhydrous........500 mg

CEFADUR 125 DT
Each dispersible uncoated tablet contains
Cefadroxil IP equivalent to
Cefadroxil (anhydrous)........125 mg
in a Flavoured base

CEFADUR- 250 DT
Each dispersible uncoated tablet contains
Cefadroxil IP equivalent to
Cefadroxil (anhydrous)........250 mg
in a Flavoured base

CEFADUR-125
Each 5ml contains
Cefadroxil IP equivalent to Cefadroxil
(anhydrous)........125 mg
In a flavour base..........q.s

CEFADUR-250
Each 5ml contains
Cefadroxil IP equivalent to Cefadroxil
(anhydrous)........125 mg
In a flavour base..........q.s

CEFADUR Rediuse Drops
Each 5ml contains
Cefadroxil IP equivalent to Cefadroxil
(anhydrous)........100 mg
In a flavour base..........q.s

Dosage Forms

Oral tablet, dispersible tablet, Rediuse suspension and drops
Pharmacology

Pharmacodynamics
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:

- *Beta-haemolytic 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. 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).

Pharmacokinetics
Absorption
After oral administration, cefadroxil is, practically, completely absorbed. Simultaneous intake of food has practically no effect on absorption (AUC).

Distribution
After oral doses of 500 mg (1,000 mg), peak plasma concentrations of about 16 (30) μg/ml are obtained after 1.1.3 hours. Between 18 and 20% of cefadroxil is bound to plasma proteins. Cephalosporins do not penetrate into the cerebrospinal fluid (CSF) and should not be used for the treatment of meningitis.

Metabolism
Cefadroxil is not metabolized.

Elimination
Cefadroxil is eliminated far more slowly than comparable oral cephalosporins (half-life: about 1.4 hours to 2.6 hours) so that intervals between doses can be prolonged to 12-24 hours. Roughly 90% of the substance is eliminated in unchanged form through the kidneys within 24 hours. Cefadroxil may be eliminated from the organism through haemodialysis.

Characteristics in Patients with Reduced Creatinine Clearance, a Sign for Renal Functional Impairment
Elimination is retarded; so, the interval between doses must be prolonged.

Indications
Treatment of the following infections caused by cefadroxil-susceptible organisms, when an oral therapy is indicated:

- Streptococcal pharyngitis and tonsillitis
- Bronchopneumonia, bacterial pneumonia
- Uncomplicated urinary tract infections-pyelonephritis, cystitis
- Skin and soft tissue infections- abscesses, furunculosis, impetigo, erysipelas, pyoderma, lymphadenitis

Consideration should be given to official local guidance regarding the appropriate use of antibacterial agents.

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 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 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.

## Dosage And Administration

The dosage depends on the susceptibility of the pathogens, the severity of the disease and on the clinical status of the patient (renal and hepatic function).

<table>
<thead>
<tr>
<th>Indication</th>
<th>Adults and adolescents &gt;40 kg with normal renal function</th>
<th>Children (&lt;40 kg) with normal renal function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Streptococcal pharyngitis/tonsillitis</strong></td>
<td>Dosage may be decreased to 1,000 mg once a day over at least 30 mg/kg/day once a day over at least 10 days</td>
<td></td>
</tr>
<tr>
<td><strong>Bronchopneumonia, bacterial pneumonia</strong></td>
<td>1,000 mg twice a day 30-50 mg/kg/day divided into two daily doses</td>
<td></td>
</tr>
<tr>
<td><strong>Urinary tract infections</strong></td>
<td>1,000 mg twice a day 30-50 mg/kg/day divided into two daily doses</td>
<td></td>
</tr>
<tr>
<td><strong>Skin and soft tissue infections</strong></td>
<td>1,000 mg twice a day 30-50 mg/kg/day divided into two daily doses</td>
<td></td>
</tr>
</tbody>
</table>

Children may benefit from increased dosage of up to 100 mg/kg/day. Depending on the severity of the infection, adults may require increased dosage. The dosage maximum is 4 g per
Chronic urinary tract infection may require a prolonged and intensive treatment with continued testing of susceptibility and clinical monitoring.

Cefadroxil 500 mg is not recommended for infants and children below 6 years of age.

For younger children and children with a body weight

**Dosage in Renal Impairment**

The dosage should be adjusted according to creatinine clearance rates to prevent accumulation of cefadroxil. In patients with creatinine clearance of ≤50 ml/min, the following reduced dosage schedule is recommended as a guideline for adults:

<table>
<thead>
<tr>
<th>Creatinine clearance (ml/min/1.73 m²)</th>
<th>Serum Creatinine (mg/100ml)</th>
<th>Initial dose (mg)</th>
<th>Following dose (mg)</th>
<th>Dosage interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-25</td>
<td>1.4-2.5</td>
<td>1,000</td>
<td>500-1000</td>
<td>Every 12 hours</td>
</tr>
<tr>
<td>25-10</td>
<td>2.5-5.6</td>
<td>1,000</td>
<td>500-1000</td>
<td>Every 24 hours</td>
</tr>
<tr>
<td>10-0</td>
<td>&gt;5.6</td>
<td>1,000</td>
<td>500-1000</td>
<td>Every 36 hours</td>
</tr>
</tbody>
</table>

Children (<40 kg) with Renal Impairment

Cefadroxil is not indicated in children suffering from renal impairment and children requiring haemodialysis.

**Geriatric**

As cefadroxil is excreted by the renal route, the dosage should be adjusted if necessary as described

**Dosage for Haemodialysis Patients**

Haemodialysis eliminates 63% of 1,000 mg of cephalosporin after 6-8 hours of haemodialysis. Elimination half-time of cephalosporin is about 3 hours during dialysis.

Patients with haemodialysis should receive one additional dose of 500-1000 mg at the end of the haemodialysis.

**Dosage in Hepatic Impairment**

No adjustment of dosage is necessary.

**Method of Administration**

Bioavailability is not affected by food and cefadroxil may be taken with meals or on an empty stomach. In case of gastrointestinal disturbances, it may be administered with food.

The tablets should be taken whole, without chewing, with a liberal quantity of fluid.

Dispersible tablet should be disperse in a teaspoonful (5ml) of boiled and cooled water before administration.

**Duration of Therapy**

Treatment should be continued for 2-3 more days after regression of the acute clinical symptoms or evidence of bacterial eradication has been obtained. In infections caused by *Streptococcus pyogenes*, up to 10 days treatment may be considered.

**Contraindications**

Cefadroxil tablets are contraindicated in patients with a known allergy to the cephalosporin group of antibiotics.
Warnings And Precautions

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, press or amines, and airway management, as clinically indicated.

Clostridium difficile-associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including cefadroxil, and may range in severity from mild diarrhoea 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 a colectomy. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over 2 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.

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 m²). 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 super-infection 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 counselled 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.

Diarrhoea 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 2 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 haematologic 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.

Drug Interactions
Cefadroxil should not be combined with bacteriostatic antibiotics (e.g. tetracycline, erythromycin, sulphonamides, chloramphenicol) since an antagonistic effect is possible.

Treatment with cefadroxil in combination with aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics should be avoided since such combinations can potentiate nephrotoxic effects.

Frequent checks on coagulation parameters are necessary during concomitant long-term use of anticoagulants or thrombocyte aggregation inhibitors to avoid haemorrhagic complications.

The concomitant administration of probenecid can produce higher and sustained concentrations of cefadroxil in the serum and in the bile.

Cefadroxil may attenuate the effect of oral contraceptives.

Cefadroxil binds to cholestyramine, which may lead to reduced bioavailability of cefadroxil.

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 foetus 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.

Lactation

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

Paediatric 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 aged 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 the greater sensitivity of some older individuals cannot be ruled out.

Cefadroxil is substantially excreted by the kidneys, and dosage adjustment is indicated for patients with 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.

Effects on the Ability to Drive and Use Machines

Cefadroxil may cause headache, dizziness, nervousness, sleeplessness and fatigue; therefore, the ability to drive and use machines may be affected.

Undesirable Effects
The adverse events are ranked under headings of frequency, using the following convention:
Very common (≥1/10); common (≥ 1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), and not known (cannot be estimated from the available data).

Adverse drug reactions that occurred in about 6-7%* of treated patients

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Common ≥1/100 to &lt;1/10</th>
<th>Uncommon ≥1/1,000 to &lt;1/100</th>
<th>Rare ≥1/10,000 to &lt;1/1,000</th>
<th>Very rare &lt;1/10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and Infestations</td>
<td>Clinical pictures due to growth of opportunistic organisms (fungi), such as vaginal mycoses, thrush</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood and Lymphatic System Disorders</td>
<td>Eosinophilia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis (rare cases during prolonged use, which subside upon discontinuation of therapy)</td>
<td></td>
<td>Haemolytic anaemia of immunologic origin</td>
<td></td>
</tr>
<tr>
<td>Immune System Disorders</td>
<td>Serum sickness-like reactions</td>
<td></td>
<td>Immediate allergic reaction (anaphylactic shock)</td>
<td></td>
</tr>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
<td>Headache, sleeplessness, dizziness, nervousness</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, glossitis</td>
<td></td>
<td>Pseudomenbranous colitis has been reported (may range in severity from mild to life-threatening)</td>
<td></td>
</tr>
<tr>
<td>Hepatobiliary Disorders</td>
<td>Cholestase and idiosyncratic hepatic failure have been reported Minor elevation of serum transaminases (AST, ALT) and alkaline phosphatases</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: The percentage may vary depending on the specific population and study.
<table>
<thead>
<tr>
<th>Skin and Subcutaneous Tissue Disorders</th>
<th>Pruritus, rash, allergic exanthema, urticaria</th>
<th>Angioneurotic edema</th>
<th>Stevens-Johnson syndrome and erythema multiforme have been reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td>Arthralgia</td>
<td></td>
</tr>
<tr>
<td>Renal and Urinary Disorders</td>
<td></td>
<td>Interstitial nephritis</td>
<td></td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
<td>Drug fever</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td>Direct and indirect positive Coombs tests</td>
<td></td>
</tr>
</tbody>
</table>

*Incidence of suspected adverse reactions in an observational postmarketing study in 904 patients.

**Overdosage**

A study of children below 6 years of age suggested that ingestion of less than 250 mg/kg of cephalosporin 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 5 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 haemodialysis session.

**Storage And Handling Instructions**

Store in cool dry place. Do not refrigerate Rediuse suspension

**Packaging Information**

| CEFADUR 500: | Strip pack of 10 tablets |
| CEFADUR 125: | Strip pack of 10 dispersible tablets |
| CEFADUR 250: | Strip pack of 10 dispersible tablets |
| CEFADUR 125: | Bottle of 30ml rediuse |
| CEFADUR 250: | Bottle of 30ml rediuse |
| CEFADUR: | Bottle of 10ml drops |

_Last updated: December 2013_
_Last reviewed: December 2013_
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