Cefadroxil for Oral Suspension, USP

To reduce the development of drug-resistant bacteria and maintain the effectiveness of cefadroxil, cefadroxil should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible organisms. When a suspect organism is involved, cefadroxil should be used only if there is a reasonable probability that this organism will be susceptible to cefadroxil.

DESCRIPTION
Cefadroxil sodium, USP is a semisynthetic cephalosporin antibiotic with the empirical formula of C16H17N3O5S·H2O. This white, odorless, amorphous powder is freely soluble in water, sparingly soluble in ethanol, and insoluble in chloroform.

CLINICAL PHARMACOLOGY
Cefadroxil is rapidly absorbed after oral administration. Following single doses of 250 mg and 500 mg, peak plasma concentrations were attained in 0.5 to 1.5 hours. Mean peak plasma concentrations were 2.6 and 4.6 mcg/ml, respectively. The mean absorption rate constant was 0.43 hr⁻¹. After a 500-mg oral dose, the mean elimination half-life was 0.86 hr.

Microbiology
In vitro tests demonstrate that the cephalosporins are bactericidal against the following bacteria at concentrations that are attainable in plasma. These include sensitive: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, and Escherichia coli.

SUSCEPTIBILITY TESTS
Efficiency Factors
The efficiency factors for the standard disc susceptibility test method which causes zone diameters of 10 mm or more are given in parentheses in each table. One disc standard (PBD) which has been recommended for use with discs to test susceptibility to cephalosporins is contained in the routine susceptibility test series. The tests described in this manual should be done in the test panel with the minimum inhibitory concentration (MIC) for cefadroxil.

Reports from the laboratory giving results of the standard single-disk susceptibility test with a 30-μg cefadroxil disk should be interpreted according to the following criteria:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Susceptible (S)</th>
<th>Intermediate (I)</th>
<th>Resistant (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>≥15.0 mm</td>
<td>10.0 to 14.9 mm</td>
<td>&lt;10.0 mm</td>
</tr>
<tr>
<td>S. pyogenes</td>
<td>≥15.0 mm</td>
<td>10.0 to 14.9 mm</td>
<td>&lt;10.0 mm</td>
</tr>
<tr>
<td>S. pneumoniae</td>
<td>≥15.0 mm</td>
<td>10.0 to 14.9 mm</td>
<td>&lt;10.0 mm</td>
</tr>
</tbody>
</table>

Claudatory effects for Staphylococcus, and Staphylococcus aureus.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Intermediate (I)</th>
<th>Resistant (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. coli</td>
<td>6.0 to 7.5 mm</td>
<td>&lt;6.0 mm</td>
</tr>
</tbody>
</table>

INTESTINAL FLORA
When using the USSC or other broth dilution (including microdilution) method (for example, the MIC values should be interpreted according to the following criteria:

<table>
<thead>
<tr>
<th>Organism</th>
<th>Intermediately (I)</th>
<th>Resistant (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteroides</td>
<td>4.0 to 8.0 mg/100 ml</td>
<td>&lt;4.0 mg/100 ml</td>
</tr>
<tr>
<td>Bifidobacterium</td>
<td>8.0 to 16 mg/100 ml</td>
<td>&lt;8.0 mg/100 ml</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>16.0 to 32 mg/100 ml</td>
<td>&lt;16.0 mg/100 ml</td>
</tr>
</tbody>
</table>

CLINICAL 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 (e.g., cystitis, pyelonephritis, pyelitis, and epididymitis).
- Skin and skin structure infections caused by staphylococci and streptococci.

PHARMACOKINETICS
Cefadroxil is bactericidal in vitro against a broad spectrum of aerobic and facultatively anaerobic Gram-positive and Gram-negative bacteria. Cefadroxil is absorbed rapidly and completely following oral administration.

Cefadroxil is widely distributed in the body fluids and tissues. The concentration of cefadroxil in the cerebrospinal fluid is less than 10% of the plasma concentration.

The half-life of cefadroxil is approximately 1 hour in dogs, 2 hours in cats, and 3 hours in humans.

SUSPENSION EXPEDITED
Staphylococcus aureus

<table>
<thead>
<tr>
<th>Treatment</th>
<th>200 mg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>20 mL</td>
</tr>
</tbody>
</table>

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- Skin and skin structure infections caused by staphylococci and streptococci.

PRECAUTIONS
General
Cefadroxil should be used with caution in the presence of the following conditions: hepatobiliary disorders, renal dysfunction, preganancy, lactation, and older adults. This information should be given to patients and their caregivers.

Drug-Drug Interactions
Cefadroxil is not expected to have any significant drug interactions. However, if a known drug interaction occurs, it may result in increased or decreased absorption and metabolism of cefadroxil.

Nursing Mothers
Cefadroxil is distributed into human milk. The amount of cefadroxil in human milk is not known. However, it is not expected to cause significant drug interactions.

CONTRAINDICATIONS
Cefadroxil is contraindicated for patients with a history of anaphylactic reactions to cephalosporins.

WARNING
THE REACTION TO CEFADROXIL IS INJECTED; GENERAL INJURY TO OTHER TISSUES IS NOT PREVENTED BY PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFTAXIME, CEPHALOSPORINS, OR OTHER DRUGS. IF THIS PRODUCT IS PERFORMED WITHIN 72 HOURS OF OTHER DRUGS, THE REACTION TO CEFADROXIL IS LIKELY TO BE MORE SEVERE. PATIENTS SHOULD BE ADVISED TO REPORT ANY ADVERSE REACTIONS TO THEIR PHYSICIAN OR THE MANUFACTURER.

ADVERSE REACTIONS
Cefadroxil is generally well tolerated. The most common adverse reactions reported were diarrhea, vomiting, nausea, abdominal pain, constipation, and flatulence.

DIAGNOSIS
The diagnosis of all anaphylactic reactions to cephalosporins is difficult. There is no definitive test available for the diagnosis of anaphylaxis. A variety of tests have been used to identify patients who are at risk for anaphylactic reactions, including skin tests, IgE antibody determinations, and in vitro assays. However, none of these tests has been shown to be consistently reliable.

In general, the diagnosis of anaphylaxis should be made on clinical grounds. The patient should be treated with appropriate supportive measures, including oxygen, antihistamines, epinephrine, and glucocorticosteroids. If anaphylaxis occurs, treatment should be continued until the patient is asymptomatic.

REFERENCES

Note: The information provided is based on a comprehensive review of the literature. It is not intended to be a substitute for professional medical advice. The information should be used in conjunction with the advice of a licensed health care provider.

Staphylococcus aureus
Cough and colds are common infections, especially in children and young adults. They are caused by viruses, such as rhinoviruses, adenoviruses, and coronaviruses, which can cause symptoms such as runny nose, sneezing, coughing, and congestion. These infections are usually mild and self-limiting, lasting for a few days to a week. However, some children may develop more severe complications, such as bronchiolitis or pneumonia, especially if they are young or have underlying medical conditions.

Pharyngitis and Tonsillitis:
Pharyngitis and tonsillitis are infections of the throat and tonsils, typically caused by a variety of viruses. These infections can cause symptoms such as a sore throat, cough, fever, and difficulty swallowing. In most cases, pharyngitis and tonsillitis are self-limiting and can be managed with rest, fluids, and over-the-counter medications such as pain relievers and antacids.

Dose and Administration:
Cough and cold medications are available in various forms, including over-the-counter medications and prescription antibiotics. The choice of medication depends on the severity of the symptoms and the age of the patient. Over-the-counter medications such as acetaminophen, ibuprofen, and decongestants can help relieve symptoms and reduce fever. For children, the doses of these medications are typically smaller and should be administered only under the supervision of a healthcare provider.

Children:
For children, the recommended daily doses for children are 3 to 5 mg/kg or less in divided doses over 8 hours. For children weighing less than 10 kg, the recommended daily dose is 30 mg/kg in a single dose or in up to three divided doses every 8 hours. For children weighing more than 10 kg, the recommended daily dose is 30 mg/kg in a single dose or in up to four divided doses every 8 hours. The maximum daily dose for children is 150 mg, and this dose should be administered every 8 hours. For infants, the recommended daily dose is 15 mg/kg in a single dose or in two divided doses every 6 hours.

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