Clindamycin Palmitate Hydrochloride for Oral Solution, USP (Pediatric)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin palmitate hydrochloride (HCl) for oral solution, USP (pediatric) and other antibacterial drugs, clindamycin palmitate HCl for oral solution, USP (pediatric) should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Not for Injection

WARNING

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

Because clindamycin therapy has been associated with severe colitis which may end fatally, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the INDICATIONS AND USAGE section. It should not be used in patients with nonbacterial infections such as most upper respiratory tract infections.

*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.

DESCRIPTION

Clindamycin palmitate hydrochloride is a water soluble hydrochloride salt of the ester of clindamycin and palmitic acid. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent compound lincomycin.

The structural formula is represented below:
The chemical name for clindamycin palmitate hydrochloride is Methyl 7-chloro-6, 7, 8-trideoxy-6-(1-methyl-trans-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-α-D-galacto-octopyranoside 2-palmitate monohydrochloride.

Clindamycin palmitate HCl for oral solution, USP (pediatric) contains clindamycin palmitate hydrochloride granules for reconstitution. Each 5 mL contains the equivalent of 75 mg clindamycin. Inactive ingredients: artificial cherry flavor, dextrin, ethylparaben, poloxamer 188, sucrose.

CLINICAL PHARMACOLOGY

Microbiology
Clindamycin inhibits bacterial protein synthesis by binding to the 50S subunit of the ribosome. It has activity against Gram-positive aerobes and anaerobes, as well as some Gram-negative anaerobes. Clindamycin is bacteriostatic. Cross-resistance between clindamycin and lincomycin is complete. Antagonism in vitro has been demonstrated between clindamycin and erythromycin. Clindamycin inducible resistance has been identified in macrolide-resistant staphylococci and beta-hemolytic streptococci. Macrolide-resistant isolates of these organisms should be screened for clindamycin inducible resistance using the D-zone test.

Clindamycin has been shown to be active against most of the isolates of the following microorganisms, both in vitro and in clinical infections, as described in the INDICATIONS AND USAGE section.

Gram-positive Aerobes
*Staphylococcus aureus* (methicillin-susceptible strains)
*Streptococcus pneumoniae* (penicillin-susceptible strains)
*Streptococcus pyogenes*

Anaerobes
*Prevotella melaninogenica*
*Fusobacterium necrophorum*
*Fusobacterium nucleatum*
*Peptostreptococcus anaerobius*
Clostridium perfringens

At least 90% of the microorganisms listed below exhibit in vitro minimum inhibitory concentrations (MICs) less than or equal to the clindamycin susceptible MIC breakpoint for organisms of a similar type to those shown in Table 2. However, the efficacy of clindamycin in treating clinical infections due to these microorganisms has not been established in adequate and well-controlled clinical trials.

**Gram-positive aerobes**
- *Staphylococcus epidermidis* (methicillin-susceptible strains)
- *Streptococcus agalactiae*
- *Streptococcus anginosus*
- *Streptococcus oralis*
- *Streptococcus mitis*

**Anaerobes**
- *Prevotella intermedia*
- *Prevotella bivia*
- *Propionibacterium acnes*
- *Micromonas (“Peptostreptococcus”) micros*
- *Finegoldia (“Peptostreptococcus”) magna*
- *Actinomyces israelii*
- *Clostridium clostridioforme*
- *Eubacterium lentum*

**Susceptibility Testing Methods**
When available, the clinical microbiology laboratory should provide cumulative in vitro susceptibility test results for antimicrobial drugs used in local hospitals and practice areas to the physician as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid the physician in selecting the most effective antimicrobial.

**Dilution Techniques**
Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized procedure based on dilution methods (broth, agar or microdilution)\(^2\)^\(^3\) or equivalent using standardized inoculum and concentrations of clindamycin. The MIC values should be interpreted according to the criteria provided in Table 2.

**Diffusion Techniques**
Quantitative methods that require the measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The standardized procedure\(^2\)^\(^4\) requires the use of standardized inoculum concentrations. This procedure uses paper disks impregnated with 2 mcg of clindamycin to test the susceptibility of microorganisms to clindamycin. Reports from the laboratory providing
results of the standard single-disk susceptibility test with a 2 mcg clindamycin disk should be interpreted according to the criteria in Table 2.

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Minimal Inhibitory Concentrations (MIC in mcg/mL)</th>
<th>Disk Diffusion (Zone Diameters in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus spp.</td>
<td>S ≤ 0.5 I 1 to 2 R ≥ 4</td>
<td>S ≥ 21 I 15 to 20 R ≤ 14</td>
</tr>
<tr>
<td>Streptococcus pneumoniae and other Streptococcus spp.</td>
<td>≤ 0.25 0.5 ≥ 1 ≥ 19 16 to 18 ≤ 15</td>
<td></td>
</tr>
<tr>
<td>Anaerobic Bacteria</td>
<td>≤ 2 4 ≥ 8 NA</td>
<td>NA NA</td>
</tr>
</tbody>
</table>

NA = not applicable

A report of “Susceptible” indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of “Intermediate” indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone that prevents small, uncontrolled technical factors from causing major discrepancies in interpretation.

A report of “Resistant” indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

**Quality Control**

Standardized susceptibility test procedures require the use of laboratory controls to monitor and ensure the accuracy and precision of the supplies and reagents used in the assay, and the techniques of the individuals performing the test. Standard clindamycin powder should provide the MIC ranges in Table 3. For the disk diffusion technique using the 2 mcg clindamycin disk the criteria provided in Table 2 should be achieved.
### Table 3. Acceptable Quality Control Ranges for Clindamycin to be Used in Validation of Susceptibility Test Results

<table>
<thead>
<tr>
<th>QC Strain</th>
<th>Acceptable Quality Control Ranges</th>
<th>Minimum Inhibitory Concentration Range (mcg/mL)</th>
<th>Disk Diffusion Range (Zone Diameters in mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enterococcus faecalis</strong></td>
<td></td>
<td>4(\text{to} \ 16)</td>
<td>NA</td>
</tr>
<tr>
<td>ATCC 29212</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td></td>
<td>0.06(\text{to} \ 0.25)</td>
<td>NA</td>
</tr>
<tr>
<td>ATCC 29213</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td></td>
<td>NA</td>
<td>24(\text{to} \ 30)</td>
</tr>
<tr>
<td>ATCC 25923</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Streptococcus pneumoniae</strong></td>
<td></td>
<td>0.03(\text{to} \ 0.12)</td>
<td>19(\text{to} \ 25)</td>
</tr>
<tr>
<td>ATCC 49619</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bacteroides fragilis</strong></td>
<td></td>
<td>0.5(\text{to} \ 2)</td>
<td>NA</td>
</tr>
<tr>
<td>ATCC 25285</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bacteroides thetaotaomicron</strong></td>
<td></td>
<td>2(\text{to} \ 8)</td>
<td>NA</td>
</tr>
<tr>
<td>ATCC 29741</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clostridium difficile</strong></td>
<td></td>
<td>2(\text{to} \ 8)</td>
<td></td>
</tr>
<tr>
<td>ATCC 700057(^1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Eggerthella lenta</strong></td>
<td></td>
<td>0.06(\text{to} \ 0.25)</td>
<td>NA</td>
</tr>
<tr>
<td>ATCC 43055</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Quality control for *C. difficile* is performed using the agar dilution method only, all other obligate anaerobes may be tested by either broth microdilution or agar diffusion methods.
NA=Not applicable
ATCC® is a registered trademark of the American Type Culture Collection

### Human Pharmacology

Blood level studies comparing clindamycin palmitate HCl with clindamycin hydrochloride show that both drugs reach their peak active serum levels at the same time, indicating a rapid hydrolysis of the palmitate to the clindamycin.

Clindamycin is widely distributed in body fluids and tissues (including bones). Approximately 10% of the biological activity is excreted in the urine. The average serum half-life after doses of clindamycin palmitate HCl is approximately two hours in pediatric patients.

Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.
Serum level studies with clindamycin palmitate HCl in normal pediatric patients weighing 50 to 100 lbs given 2, 3 or 4 mg/kg every 6 hours (8, 12 or 16 mg/kg/day) demonstrated mean peak clindamycin serum levels of 1.24, 2.25 and 2.44 mcg/mL respectively, one hour after the first dose. By the fifth dose, the 6-hour serum concentration had reached equilibrium. Peak serum concentrations after this time would be about 2.46, 2.98 and 3.79 mcg/mL with doses of 8, 12 and 16 mg/kg/day, respectively.

Serum levels have been uniform and predictable from person to person and dose to dose. Multiple-dose studies in neonates and infants up to 6 months of age show that the drug does not accumulate in the serum and is excreted rapidly. Serum levels exceed the MICs for most indicated organisms for at least six hours following administration of the usually recommended doses of clindamycin palmitate HCl in adults and pediatric patients.

No significant levels of clindamycin are attained in the cerebrospinal fluid, even in the presence of inflamed meninges.

Pharmacokinetic studies in elderly volunteers (61 to 79 years) and younger adults (18 to 39 years) indicate that age alone does not alter clindamycin pharmacokinetics (clearance, elimination half-life, volume of distribution, and area under the serum concentration-time curve) after IV administration of clindamycin phosphate.

After oral administration of clindamycin hydrochloride, elimination half-life is increased to approximately 4.0 hours (range 3.4 to 5.1 h) in the elderly compared to 3.2 hours (range 2.1 to 4.2 h) in younger adults; administration of clindamycin palmitate HCl resulted in a similar elimination half-life value of about 4.5 hours in elderly subjects. However, the extent of absorption is not different between age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function1.

INDICATIONS AND USAGE

Clindamycin palmitate HCl for oral solution, USP (pediatric) is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin is also indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci and staphylococci. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. Because of the risk of colitis, as described in the WARNING box, before selecting clindamycin the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin).

Anaerobes: Serious respiratory tract infections such as empyema, anaerobic pneumonitis and lung abscess; serious skin and soft tissue infections; septicemia; intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms resident in the normal gastrointestinal tract); infections of the female
pelvis and genital tract such as endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis and postsurgical vaginal cuff infection.

**Streptococci:** Serious respiratory tract infections; serious skin and soft tissue infections.

**Staphylococci:** Serious respiratory tract infections; serious skin and soft tissue infections.

**Pneumococci:** Serious respiratory tract infections.

Bacteriologic studies should be performed to determine the causative organisms and their susceptibility to clindamycin.

**In Vitro Susceptibility Testing**

A standardized disk testing procedure\(^2\) is recommended for determining susceptibility of aerobic bacteria to clindamycin. A description is contained in the clindamycin palmitate HCl susceptibility disk insert. Using this method, the laboratory can designate isolates as resistant, intermediate, or susceptible. Tube or agar dilution methods may be used for both anaerobic and aerobic bacteria. When the directions in the clindamycin palmitate HCl susceptibility powder insert are followed, an MIC (minimal inhibitory concentration) of 1.6 mcg/mL may be considered susceptible; MICs of 1.6 to 4.8 mcg/mL may be considered intermediate and MICs greater than 4.8 mcg/mL may be considered resistant.

Clindamycin palmitate HCl susceptibility disks 2 mcg. See package insert for use.

Clindamycin palmitate HCl susceptibility powder 20 mg. See package insert for use.

For anaerobic bacteria the minimal inhibitory concentration (MIC) of clindamycin can be determined by agar dilution and broth dilution (including microdilution) techniques. If MICs are not determined routinely, the disk broth method is recommended for routine use. THE KIRBY-BAUER DISK DIFFUSION METHOD AND ITS INTERPRETIVE STANDARDS ARE NOT RECOMMENDED FOR ANAEROBES.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin palmitate HCl for oral solution, USP (pediatric) and other antibacterial drugs, clindamycin palmitate HCl for oral solution, USP (pediatric) 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**

This drug is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.
WARNINGS

See WARNING box.

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

A careful inquiry should be made concerning previous sensitivities to drugs and other allergens.

*Usage in Meningitis:* Since clindamycin does not diffuse adequately into the cerebrospinal fluid, the drug should not be used in the treatment of meningitis.

PRECAUTIONS

General

Review of experience to date suggests that a subgroup of older patients with associated severe illness may tolerate diarrhea less well. When clindamycin is indicated in these patients, they should be carefully monitored for change in bowel frequency.

Clindamycin palmitate HCl should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Clindamycin palmitate HCl should be prescribed with caution in atopic individuals.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

The use of clindamycin palmitate HCl occasionally results in overgrowth of nonsusceptible organisms—particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.
Clindamycin dosage modification may not be necessary in patients with renal disease. In patients with moderate to severe liver disease, prolongation of clindamycin half-life has been found. However, it was postulated from studies that when given every eight hours, accumulation should rarely occur. Therefore, dosage modification in patients with liver disease may not be necessary. However, periodic liver enzyme determinations should be made when treating patients with severe liver disease.

Prescribing clindamycin palmitate HCl 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.

**Information for Patients**

Patients should be counseled that antibacterial drugs including clindamycin palmitate HCl should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When clindamycin palmitate HCl 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 clindamycin palmitate HCl 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.

**Laboratory Tests**

During prolonged therapy, periodic liver and kidney function tests and blood counts should be performed.

**Drug Interactions**

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, it should be used with caution in patients receiving such agents.

Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*. Because of possible clinical significance, these two drugs should not be administered concurrently.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential. Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.6 times the highest recommended adult human oral dose based on mg/m²) revealed no effects on fertility or mating ability.

**Pregnancy: Teratogenic Effects**

Pregnancy Category B

Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day (3.2 and 1.6 times the highest recommended adult human oral dose based on mg/m², respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (1.3 and 0.7 times the highest recommended adult human oral dose based on mg/m², respectively) revealed no evidence of teratogenicity.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of the human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers**

Clindamycin has been reported to appear in breast milk in the range of 0.7 to 3.8 mcg/mL.

**Pediatric Use**

When clindamycin palmitate HCl is administered to the pediatric population (birth to 16 years), appropriate monitoring of organ system functions is desirable.

**Geriatric Use**

Clinical studies of clindamycin did not include sufficient numbers of patients age 65 and over to determine whether they respond differently from younger patients. However, other reported clinical experience indicates that antibiotic-associated colitis and diarrhea (due to *Clostridium difficile*) seen in association with most antibiotics occur more frequently in the elderly (>60 years) and may be more severe. These patients should be carefully monitored for the development of diarrhea.

Pharmacokinetic studies with clindamycin have shown no clinically important differences between young subjects (18 to 39 years) and elderly subjects (61 to 79 years) with normal hepatic function and normal (age-adjusted) renal function after oral or intravenous administration.
ADVERSE REACTIONS

The following reactions have been reported with the use of clindamycin.

Gastrointestinal: Abdominal pain, pseudomembranous colitis, esophagitis, nausea, vomiting and diarrhea (see WARNING box). The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment (see WARNINGS).

Hypersensitivity Reactions: Generalized mild to moderate morbilliform-like (maculopapular) skin rashes are the most frequently reported adverse reactions. Vesiculobullous rashes, as well as urticaria, have been observed during drug therapy. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions have also been reported.

Skin and Mucous Membranes: Pruritus, vaginitis, and rare instances of exfoliative dermatitis have been reported. (See Hypersensitivity Reactions.)

Liver: Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy.

Renal: Although no direct relationship of clindamycin to renal damage has been established, renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances.

Hematopoietic: Transient neutropenia (leukopenia) and eosinophilia have been reported. Reports of agranulocytosis and thrombocytopenia have been made. No direct etiologic relationship to concurrent clindamycin therapy could be made in any of the foregoing.

Musculoskeletal: Rare instances of polyarthritis have been reported.

OVERDOSAGE

Significant mortality was observed in mice at an intravenous dose of 855 mg/kg and in rats at an oral or subcutaneous dose of approximately 2618 mg/kg. In the mice, convulsions and depression were observed. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

DOSAGE AND ADMINISTRATION

If significant diarrhea occurs during therapy, this antibiotic should be discontinued (see WARNING box).

Concomitant administration of food does not adversely affect the absorption of clindamycin palmitate HCl contained in clindamycin palmitate HCl for oral solution, USP (pediatric).
Serious infections: 8 to 12 mg/kg/day (4 to 6 mg/lb/day) divided into 3 or 4 equal doses.

Severe infections: 13 to 16 mg/kg/day (6.5 to 8 mg/lb/day) divided into 3 or 4 equal doses.

More severe infections: 17 to 25 mg/kg/day (8.5 to 12.5 mg/lb/day) divided into 3 or 4 equal doses.

In pediatric patients weighing 10 kg or less, ½ teaspoon (37.5 mg) three times a day should be considered the minimum recommended dose.

Serious infections due to anaerobic bacteria are usually treated with clindamycin injection. However, in clinically appropriate circumstances, the physician may elect to initiate treatment or continue treatment with clindamycin palmitate HCl for oral solution, USP (pediatric).

**NOTE:** In cases of β-hemolytic streptococcal infections, treatment should be continued for at least 10 days.

**Reconstitution Instructions:** When reconstituted with water as follows, each 5 mL (teaspoon) of solution contains clindamycin palmitate HCl equivalent to 75 mg clindamycin.

Reconstitute bottles of 100 mL with **75 mL** of water. Add a large portion of the water and shake vigorously; add the remainder of the water and shake until the solution is uniform.

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

Do **NOT** refrigerate the reconstituted solution; when chilled, the solution may thicken and be difficult to pour. The solution is stable for 2 weeks at room temperature.

**HOW SUPPLIED**

Clindamycin palmitate HCl for oral solution, USP (pediatric) is a white to off-white powder forming a clear colorless cherry flavored solution upon constitution with water. When reconstituted as directed, each bottle yields 100 mL of solution containing 75 mg of clindamycin per 5 mL (NDC 65162-468-19).

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

**ANIMAL TOXICOLOGY**
One year oral toxicity studies in Spartan Sprague-Dawley rats and beagle dogs at dose levels up to 300 mg/kg/day (approximately 1.6 and 5.4 times the highest recommended adult human oral dose based on mg/m², respectively) have shown clindamycin to be well tolerated. No appreciable difference in pathological findings has been observed between groups of animals treated with clindamycin and comparable control groups. Rats receiving clindamycin hydrochloride at 600 mg/kg/day (approximately 3.2 times the highest recommended adult human oral dose based on mg/m²) for 6 months tolerated the drug well; however, dogs dosed at this level (approximately 10.8 times the highest recommended adult human oral dose based on mg/m²) vomited, would not eat, and lost weight.

Rx only

References


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