

**CLINDAMYCIN PHOSPHATE - clindamycin phosphate injection, solution**  
**Physicians Total Care, Inc.**

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**Fliptop Vial**

R<sub>x</sub> only

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

**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 Injection, USP, a water soluble ester of clindamycin and phosphoric acid, is a sterile solution for intramuscular or intravenous use.

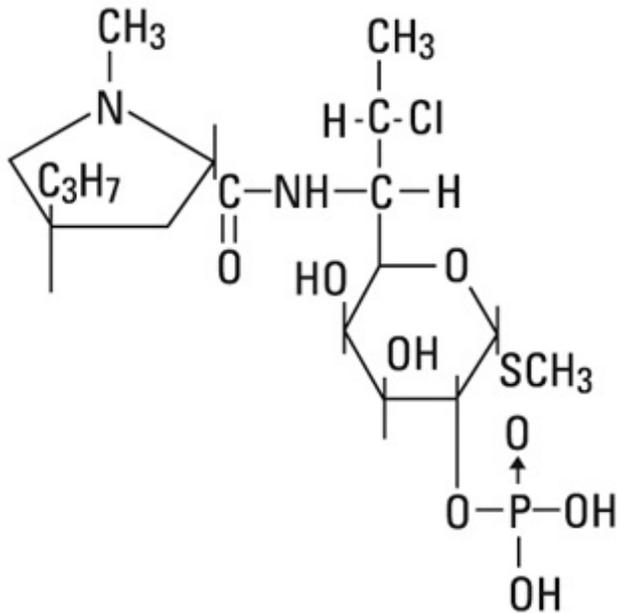
May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. pH is 6.5 range 5.5 to 7.0.

Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chloro-substitution of the 7 (R)-hydroxyl group of the parent compound lincomycin.

The chemical name of clindamycin phosphate is methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-*trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*- $\alpha$ -D-*galacto*-octopyranoside 2-(dihydrogen phosphate).

The molecular formula is C<sub>18</sub>H<sub>34</sub>ClN<sub>2</sub>O<sub>8</sub>PS and the molecular weight is 504.97.

The structural formula is represented below:



Each mL contains clindamycin phosphate equivalent to 150 mg clindamycin, 0.5 mg disodium edetate and 9.45 mg benzyl alcohol added as a preservative.

## CLINICAL PHARMACOLOGY

Biologically inactive clindamycin phosphate is rapidly converted to active clindamycin.

By the end of short-term intravenous infusion, peak serum levels of active clindamycin are reached. Biologically inactive clindamycin phosphate disappears rapidly from the serum; the average elimination half-life is 6 minutes; however, the serum elimination half-life of active clindamycin is about 3 hours in adults and 2½ hours in pediatric patients.

After intramuscular injection of clindamycin phosphate, peak levels of active clindamycin are reached within 3 hours in adults and 1 hour in pediatric patients. Serum level curves may be constructed from I.V. peak serum levels as given in Table 1 by application of elimination half-lives listed above.

Serum levels of clindamycin can be maintained above the *in vitro* minimum inhibitory concentrations for most indicated organisms by administration of clindamycin phosphate every 8 to 12 hours in adults and every 6 to 8 hours in pediatric patients, or by continuous intravenous infusion. An equilibrium state is reached by the third dose.

The elimination half-life of clindamycin is increased slightly in patients with markedly reduced renal or hepatic function. Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum. Dosage schedules need not be modified in the presence of mild or moderate renal or hepatic disease.

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 I.V. administration of clindamycin phosphate. After oral administration of clindamycin hydrochloride, elimination half-life is increased to approximately 4 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. The extent of absorption, however, is not different between the age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function<sup>1</sup>.

Serum assays for active clindamycin require an inhibitor to prevent *in vitro* hydrolysis of clindamycin phosphate.

**Table 1 Average Peak and Trough Serum Concentrations of Active Clindamycin After Dosing with Clindamycin Phosphate**

<b>Dosage Regimen</b>	<b>Peak mcg/mL</b>	<b>Trough mcg/mL</b>
<b>Healthy Adult Males (Post equilibrium)</b>		
600 mg I.V. in 30 min q6h	10.9	
600 mg I.V. in 30 min q8h	10.8	2
900 mg I.V. in 30 min q8h	14.1	1.1
600 mg I.M. q12*	9	1.7
<b>Pediatric Patients (first dose)*</b>		
5-7 mg/kg I.V. in 1 hour	10	
5-7 mg/kg I.M.	8	
3-5 mg/kg I.M.	4	

\*Data in this group from patients being treated for infection.

**Microbiology:** Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin.

Clindamycin has been shown to have *in vitro* activity against isolates of the following organisms:

*Aerobic gram positive cocci*, including:

*Staphylococcus aureus* (penicillinase and non-penicillinase producing strains). When tested by *in vitro* methods, some staphylococcal strains

originally resistant to erythromycin rapidly develop resistance to clindamycin.

*Staphylococcus epidermidis* (penicillinase and non-penicillinase producing strains). When tested by *in vitro* methods, some staphylococcal strains

originally resistant to erythromycin rapidly develop resistance to clindamycin.

Streptococci (except *Enterococcus faecalis*)

Pneumococci

*Anaerobic gram negative bacilli*, including:

*Bacteroides species* (including *Bacteroides fragilis* group and *Bacteroides melaninogenicus* group)

*Fusobacterium species*

*Anaerobic gram positive nonsporeforming bacilli*, including:

*Propionibacterium*

*Eubacterium*

*Actinomyces species*

*Anaerobic and microaerophilic gram positive cocci*, including:

*Peptococcus species*

*Peptostreptococcus species*

Microaerophilic streptococci

*Clostridia*: Clostridia are more resistant than most anaerobes to clindamycin. Most *Clostridium perfringens* are susceptible, but other species, e.g.,

*Clostridium sporogenes* and *Clostridium tertium* are frequently resistant to clindamycin. Susceptibility testing should be done.

Cross resistance has been demonstrated between clindamycin and lincomycin.

Antagonism has been demonstrated between clindamycin and erythromycin.

### In vitro **Susceptibility Testing:**

Disk diffusion technique-Quantitative methods that require measurement of zone diameters give the most precise estimates of antibiotic susceptibility. One such procedure<sup>2</sup> has been recommended for use with disks to test susceptibility to clindamycin.

Reports from a laboratory using the standardized single-disk susceptibility test<sup>1</sup> with a 2 mcg clindamycin disk should be interpreted according to the following criteria:

Susceptible organisms produce zones of 17 mm or greater, indicating that the tested organism is likely to respond to therapy.

Organisms of intermediate susceptibility produce zones of 15-16 mm, indicating that the tested organism would be susceptible if a high dosage is used or if the infection is confined to tissues and fluids (e.g., urine), in which high antibiotic levels are attained.

Resistant organisms produce zones of 14 mm or less, indicating that other therapy should be selected.

Standardized procedures require the use of control organisms. The 2 mcg clindamycin disk should give a zone diameter between 24 and 30 mm for *S. aureus* ATCC 25923.

Dilution techniques – A bacterial isolate may be considered susceptible if the minimum inhibitory concentration (MIC) for clindamycin is not more than 1.6 mcg/mL. Organisms are considered moderately susceptible if the MIC is greater than 1.6 mcg/mL and less than or equal to 4.8 mcg/mL. Organisms are considered resistant if the MIC is greater than 4.8 mcg per mL. The range of MIC's for the control strains are as follows:

*S. aureus* ATCC 29213, 0.06 to 0.25 mcg/mL.

*E. faecalis* ATCC 29212, 4 to 16 mcg/mL.

For anaerobic bacteria the minimum inhibitory concentration (MIC) of clindamycin can be determined by agar dilution and broth dilution (including microdilution) techniques.<sup>3</sup> 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.**

## **INDICATIONS AND USAGE**

Clindamycin Injection, USP is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin Injection, USP 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 antibiotic-associated pseudomembranous 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).

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

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

Clindamycin Injection, USP is indicated in the treatment of serious infections caused by susceptible strains of the designated organisms in the conditions listed below:

Lower respiratory tract infections including pneumonia, empyema, and lung abscess caused by anaerobes, *Streptococcus pneumoniae*, other streptococci (except *E. faecalis*), and *Staphylococcus aureus*.

Skin and skin structure infections caused by *Streptococcus pyogenes*, *Staphylococcus aureus*, and anaerobes.

Gynecological infections including endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis, and postsurgical vaginal cuff infection caused by susceptible anaerobes.

Intra-abdominal infections including peritonitis and intra-abdominal abscess caused by susceptible anaerobic organisms.

Septicemia caused by *Staphylococcus aureus*, streptococci (except *Enterococcus faecalis*), and susceptible anaerobes.

Bone and joint infections including acute hematogenous osteomyelitis caused by *Staphylococcus aureus* and as adjunctive therapy in the surgical treatment of chronic bone and joint infections due to susceptible organisms.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin and other antibacterial drugs, clindamycin 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, 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.

This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with a fatal "Gasping Syndrome" in premature infants. (See PRECAUTIONS– **Pediatric Use**).

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

SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN AND INTRAVENOUS CORTICOSTEROIDS SHOULD ALSO BE ADMINISTERED AS INDICATED.

## **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 phosphate should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Clindamycin phosphate should be prescribed with caution in atopic individuals.

Certain infections may require incision and drainage or other indicated surgical procedures in addition to antibiotic therapy.

The use of clindamycin phosphate may result in overgrowth of nonsusceptible organisms— particularly yeasts. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Clindamycin phosphate should not be injected intravenously undiluted as a bolus, but should be infused over at least 10-60 minutes as directed in the DOSAGE AND ADMINISTRATION section.

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 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 should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When clindamycin 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 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, the 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 1.1 times the highest recommended adult human dose based on mg/m<sup>2</sup>) 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 (2.1 and 1.1 times the highest recommended adult human dose based on mg/m<sup>2</sup>, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (0.9 and 0.5 times the highest recommended adult human dose based on mg/m<sup>2</sup>, 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 it is clearly needed.

Nursing Mothers

Clindamycin has been reported to appear in breast milk in the range of 0.7 to 3.8 mcg/mL at dosages of 150 mg orally to 600 mg intravenously. Because of the potential for adverse reactions due to clindamycin in neonates (see **Pediatric Use**), the decision to discontinue the drug should be made, taking into account the importance of the drug to the mother.

Pediatric Use

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

Usage in Newborns and Infants

This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with a fatal "Gasping Syndrome" in premature infants.

The potential for the toxic effect in the pediatric population from chemicals that may leach from the single dose premixed IV preparation in plastic has not been evaluated.

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 and elderly subjects 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:** Antibiotic-associated colitis (see WARNINGS), pseudomembranous colitis abdominal pain, nausea and vomiting. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment (see WARNINGS). An unpleasant or metallic taste occasionally has been reported after intravenous administration of the higher doses of clindamycin phosphate.

**Hypersensitivity Reactions:** Maculopapular rash and urticaria have been observed during drug therapy. Generalized mild to moderate morbilliform-like skin rashes are the most frequently reported of

all adverse reactions. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with clindamycin. A few cases of anaphylactoid reactions have been reported. If a hypersensitivity reaction occurs, the drug should be discontinued. The usual agents (epinephrine, corticosteroids, antihistamines) should be available for emergency treatment of serious reactions.

**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.

**Local Reactions:** Pain, induration and sterile abscess have been reported after intramuscular injection and thrombophlebitis after intravenous infusion. Reactions can be minimized or avoided by giving deep intramuscular injections and avoiding prolonged use of indwelling intravenous catheters.

**Musculoskeletal:** Rare instances of polyarthritides have been reported.

**Cardiovascular:** Rare instances of cardiopulmonary arrest and hypotension have been reported following too rapid intravenous administration. (See **DOSAGE AND ADMINISTRATION**).

## 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 diarrhea occurs during therapy, this antibiotic should be discontinued. (See **WARNING** box).

### Adults:

Parenteral (I.M. or I.V. Administration):

Serious infections due to aerobic gram-positive cocci and the more susceptible anaerobes (NOT generally including *Bacteroides fragilis*, *Peptococcus* species and *Clostridium* species other than *Clostridium perfringens*):

600 to 1200 mg/day in 2, 3 or 4 equal doses.

More severe infections, particularly those due to proven or suspected *Bacteroides fragilis*, *Peptococcus* species, or *Clostridium* species other than *Clostridium perfringens*:

1200 to 2700 mg/day in 2, 3 or 4 equal doses.

For more serious infections, these doses may have to be increased. In life-threatening situations due to either aerobes or anaerobes, these doses may be increased. Doses of as much as 4800 mg daily have been given intravenously to adults. See **Dilution and Infusion Rates** section below.

Single I.M. injections of greater than 600 mg are not recommended.

Alternatively, drug may be administered in the form of a single rapid infusion of the first dose followed by continuous I.V. infusion as follows:

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To maintain serum clindamycin levels	Rapid infusion rate	Maintenance infusion rate
Above 4 mcg/mL	10 mg/min for 30 min	0.75 mg/min
Above 5 mcg/mL	15 mg/min for 30 min	1 mg/min
Above 6 mcg/mL	20 mg/min for 30 min	1.25 mg/min

### Neonates (less than 1 month):

15 to 20 mg/kg/day in three to four equal doses. The lower dosage may be adequate for small prematures.

### Pediatric patients (1 month of age to 16 years):

Parenteral (I.M. or I.V.) administration: 20 to 40 mg/kg/day in 3 or 4 equal doses. The higher doses would be used for more severe infections. As an alternative to dosing on a body weight basis, pediatric patients may be dosed on the basis of square meters body surface: 350 mg/m<sup>2</sup>/day for serious infections and 450 mg/m<sup>2</sup>/day for more severe infections.

Parenteral therapy may be changed to clindamycin palmitate hydrochloride for oral solution or clindamycin hydrochloride capsules when the condition warrants and at the discretion of the physician.

In cases of  $\beta$ -hemolytic streptococcal infections, treatment should be continued for at least 10 days.

### Dilution and Infusion Rates:

**Clindamycin phosphate must be diluted prior to I.V. administration. The concentration of clindamycin in diluent for infusion should not exceed 18 mg per mL. Infusion rates should not exceed 30 mg per minute.** The usual infusion dilutions and rates are as follows:

Dose	Diluent	Time
300 mg	50 mL	10 min
600 mg	50 mL	20 min
900 mg	50-100 mL	30 min
1200 mg	100 mL	40 min

Administration of more than 1200 mg in a single 1-hour infusion is not recommended.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

### Dilution and Compatibility:

Physical and biological compatibility studies monitored for 24 hours at room temperature have demonstrated no inactivation or incompatibility with the use of clindamycin phosphate in I.V. solutions containing sodium chloride, glucose, calcium or potassium, and solutions containing vitamin B complex in concentrations usually used clinically. No incompatibility has been demonstrated with the antibiotics cephalothin, kanamycin, gentamicin, penicillin or carbenicillin.

The following drugs are physically incompatible with clindamycin phosphate: ampicillin sodium, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, and magnesium sulfate.

The compatibility and duration of stability of drug admixtures will vary depending on concentration and other conditions.

### Physico-Chemical Stability of Diluted Solutions of Clindamycin:

Room temperature: 6, 9, and 12 mg/mL (equivalent to clindamycin base) in 5% Dextrose Injection, 0.9% Sodium Chloride Injection, or Lactated Ringer's Injection in glass bottles or minibags, demonstrated

physical and chemical stability for at least 16 days at 25°C. Also, 18 mg/mL (equivalent to clindamycin base) in 5% Dextrose Injection, in minibags, demonstrated physical and chemical stability for at least 16 days at 25°C.

Refrigeration: 6, 9 and 12 mg/mL (equivalent to clindamycin base) in 5% Dextrose Injection, 0.9% Sodium Chloride Injection, or Lactated Ringer's Injection in glass bottles or minibags, demonstrated physical and chemical stability for at least 32 days at 4°C.

**IMPORTANT:** This chemical stability information in no way indicates that it would be acceptable practice to use this product well after the preparation time. Good professional practice suggests that compounded admixtures should be administered as soon after preparation as is feasible.

Frozen: 6, 9 and 12 mg/mL (equivalent to clindamycin base) in 5% Dextrose Injection, 0.9% Sodium Chloride Injection, or Lactated Ringer's Injection in minibags demonstrated physical and chemical stability for at least eight weeks at -10°C.

Frozen solutions should be thawed at room temperature and not refrozen.

**Caution:** Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is complete.

## HOW SUPPLIED

Clindamycin Injection, USP (150 mg/mL) is supplied as follows:

List No.	Volume	Type Container	Clindamycin base Total Content
54868-3695-0	2 mL	Single-dose fliptop vial/ 25 vials per tray	300 mg

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

Do not refrigerate.

## 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 1.1 and 3.6 times the highest recommended adult human dose based on mg/m<sup>2</sup>, 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 2.1 times the highest recommended adult human dose based on mg/m<sup>2</sup>) for 6 months tolerated the drug well; however, dogs dosed at this level (approximately 7.2 times the highest recommended adult human dose based on mg/m<sup>2</sup>) vomited, would not eat, and lost weight.

Revised: March, 2008

## REFERENCES

1. Smith RB, Phillips JP: Evaluation of Clindamycin Hydrochloride and Clindamycin Phosphate in an Aged Population. Upjohn TR:8147-9122-021, December 1982.
2. Bauer AW, Kirby WMM, Sherris JC, Turck M: Antibiotic susceptibility testing by a standardized single disk method, *Am J Clin Path*, 45:493-496, 1966. Standardized Disk Susceptibility Test, *Federal Register* 37:20527-29, 1972.
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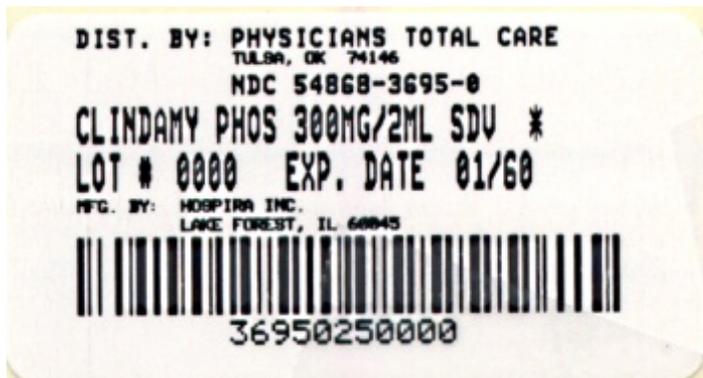
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Physicians Total Care, Inc.  
Tulsa, OK 74146

### PRINCIPAL DISPLAY PANEL

Clindamycin Injection, USP (300 mg/2 mL)



## CLINDAMYCIN PHOSPHATE

clindamycin phosphate injection, solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:54868-3695(NDC:0409-4050-01)
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN PHOSPHATE	150 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.5 mg in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	9.45 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3695-0	1 in 1 CASE		
1		25 in 1 TRAY		
1		2 mL in 1 VIAL, SINGLE-DOSE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA062801	02/27/1997	

**Labeler** - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

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Physicians Total Care, Inc.