CLINDAMYCIN PHOSPHATE- clindamycin phosphate injection, solution
ALMAJECT, INC.

Clindamycin Injection, USP

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

Sterile Solution is for Intramuscular and Intravenous Use

WARNING

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

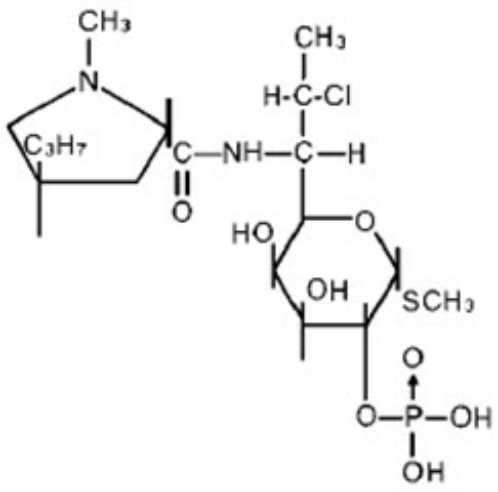
DESCRIPTION

Clindamycin Injection, USP in vials contains clindamycin phosphate, a water soluble ester of clindamycin and phosphoric acid. Each mL contains the equivalent of 150 mg clindamycin, 0.5 mg disodium edetate and 9.45 mg benzyl alcohol added as preservative in each mL. 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 L-*threo*-α-D-*galacto*-Octopyranoside, methyl-7-chloro-6,7,8-trideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl] amino]-1-thio-, 2-(dihydrogen phosphate), (2*S*-*trans*)-.

The molecular formula is $C_{18}H_{34}ClN_2O_8PS$ and the molecular weight is 504.96.

The structural formula is represented below:



CLINICAL PHARMACOLOGY

Distribution

Biologically inactive clindamycin phosphate is converted to active clindamycin. By the end of short-term intravenous infusion, peak serum concentrations of active clindamycin are reached.

After intramuscular injection of clindamycin phosphate, peak concentrations of active clindamycin are reached within 3 hours in adults and 1 hour in pediatric patients.

Serum concentrations 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.

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

Metabolism

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly metabolized by Cytochrome P450 3A4 (CYP3A4), with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin.

Excretion

Biologically inactive clindamycin phosphate disappears from the serum with 6 minutes of the average elimination half-life; however, the average serum elimination half-life of active clindamycin is about 3 hours in adults and 2½ hours in pediatric patients.

Specific Populations

Patients with Renal/Hepatic Impairment

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 patients with renal or hepatic disease.

Geriatric Patients

Pharmacokinetic studies in elderly volunteers (61–79 years) and younger adults (18–39 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, the average elimination half-life is increased to approximately 4.0 hours (range 3.4–5.1 h) in the elderly, compared to 3.2 hours (range 2.1–4.2 h) in younger adults. The extent of absorption, however, is not different between age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function[1].

Pharmacokinetics in Pediatric Patients with PMA ≤32 weeks, or >32 to ≤40 weeks

Systemic clearance (CL) in premature infants increases with increases in body weight (kg) and post-menstrual age (PMA). The dosing regimens for pediatric patients ≤32 weeks PMA (5 mg/kg) and >32 to ≤40 weeks PMA (7 mg/kg), both administered intravenously every 8 hours, achieve exposures comparable to therapeutic exposures in adults (weighing 70 kg) administered clindamycin 600 mg every 8 hours (Table 1).

Table 1: Predicted Drug Exposure (Mean ± SD) of Clindamycin in Adults and in Pediatric Patients with PMA ≤32 weeks, or >32 to ≤40 weeks

Age	Adult (70 kg)	PMA ≤32 weeks	PMA>32 – ≤40 weeks
Dose (every 8 hours)	600 mg	5 mg/kg	7 mg/kg
$AUC_{ss,0–8\ hour}$ (mcg·h/mL)	50.5 (30.95)	52.5 (17.0)	55.9 (23.55)
$C_{max,ss}$ (mcg/mL)	12.0 (3.49)	9.0 (2.02)	10.5 (2.79)
$C_{min,ss}$ (mcg/mL)	3.1 (3.34)	4.6 (2.00)	4.4 (2.77)

PMA: post-menstrual age; $AUC_{ss,0–8\ hour}$: area under the concentration-time curve during a dosing interval at steady state; $C_{max,ss}$: maximum drug concentration at steady state; $C_{min,ss}$: minimum or trough drug concentration at steady state.

Obese Pediatric Patients Aged 2 to Less than 18 Years and Obese Adults Aged 18 to 20 Years

An analysis of pharmacokinetic data in obese pediatric patients aged 2 to less than 18 years and obese adults aged 18 to 20 years demonstrated that clindamycin clearance and volume of distribution, normalized by total body weight, are comparable regardless of obesity.

Microbiology

Mechanism of Action

Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic.

Resistance

Resistance to clindamycin is most often caused by modification of specific bases of the 23S ribosomal RNA. Cross-resistance between clindamycin and lincomycin is complete. Because the binding sites for these antibacterial drugs overlap, cross-resistance is sometimes observed among lincosamides, macrolides and streptogramin B. Macrolide-inducible resistance to clindamycin occurs in some isolates of macrolide-resistant bacteria. Macrolide-resistant isolates of staphylococci and beta-hemolytic streptococci should be screened for induction of clindamycin resistance using the D-zone test.

Antimicrobial Activity

Clindamycin has been shown to be active against most of the isolates of the following microorganisms, both in vitro and in clinical infections *[*see **INDICATIONS AND USAGE** *]*:

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible strains)
Streptococcus pneumoniae (penicillin-susceptible strains)
Streptococcus pyogenes

Anaerobic bacteria

Clostridium perfringens
Fusobacterium necrophorum
Fusobacterium nucleatum
Peptostreptococcus anaerobius
Prevotella melaninogenica

The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following bacteria exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for clindamycin against isolates of a similar genus or organism group. However, the efficacy of clindamycin in treating clinical infections due to these bacteria has not been established in adequate and well-controlled clinical trials.

Gram-positive bacteria

Staphylococcus epidermidis (methicillin-susceptible strains)
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus mitis
Streptococcus oralis

Anaerobic bacteria

Actinomyces israelii
Clostridium clostridioforme
Eggerthella lenta
Finegoldia (Peptostreptococcus) magna
Micromonas (Peptostreptococcus) micros
Prevotella bivia
Prevotella intermedia
Propionibacterium acnes

Susceptibility Testing

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

Clindamycin phosphate products are indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin phosphate products are 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 **BOXED WARNING**, 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 phosphate 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 phosphate and other antibacterial drugs, clindamycin phosphate 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 **BOXED WARNING**.

Clostridioides difficile Associated Diarrhea

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

Anaphylactic and Severe Hypersensitivity Reactions

Anaphylactic shock and anaphylactic reactions have been reported **(**see **ADVERSE REACTIONS)**.

Severe hypersensitivity reactions, including severe skin reactions such as toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and Stevens-Johnson syndrome (SJS), some with fatal outcome, have been reported **(**see **ADVERSE REACTIONS)**.

In case of such an anaphylactic or severe hypersensitivity reaction, discontinue treatment permanently and institute appropriate therapy.

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

Benzyl Alcohol Toxicity in Neonates ("Gasping Syndrome")

This product contains benzyl alcohol as a preservative. The administration of intravenous solutions containing the preservative benzyl alcohol has been associated with the "gasping syndrome", and death in neonates. Symptoms include a striking onset of gasping respiration, hypotension, bradycardia, and cardiovascular collapse. Although the normal therapeutic dose of this product delivers amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known and total daily benzyl alcohol exposure may be increased by concomitant medications.

The risk of benzyl alcohol toxicity depends on the quantity administered and the liver and kidneys' capacity to detoxify the chemical. Premature and low birth weight infants may be more likely to develop toxicity.

Renal Toxicity

Clindamycin is potentially nephrotoxic. Acute kidney injury including acute renal failure has been reported. Therefore, monitoring of renal function should be considered during therapy of patients with pre-existing renal dysfunction or taking concomitant nephrotoxic drugs and monitoring of renal function should be performed if therapy is prolonged.

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 phosphate products 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 is not 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 phosphate 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 phosphate should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When clindamycin phosphate 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 phosphate 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.

Clindamycin is metabolized predominantly by CYP3A4, and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N-desmethylclindamycin. Therefore, inhibitors of CYP3A4 and CYP3A5 may increase plasma concentrations of clindamycin and inducers of these isoenzymes may reduce plasma concentrations of clindamycin. In the presence of strong CYP3A4 inhibitors, monitor for adverse reactions. In the presence of strong CYP3A4 inducers such as rifampicin, monitor for loss of effectiveness.

In vitro studies indicate that clindamycin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2E1 or CYP2D6 and only moderately inhibits CYP3A4.

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^2) revealed no effects on fertility or mating ability.

Pregnancy

Teratogenic effects

In clinical trials with pregnant women, the systemic administration of clindamycin during the second and third trimesters, has not been associated with an increased frequency of congenital abnormalities.

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

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^2, 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^2, respectively) revealed no evidence of teratogenicity.

Clindamycin Injection contains benzyl alcohol. Benzyl alcohol can cross the placenta (see **WARNINGS)**.

Nursing Mothers

Limited published data based on breast milk sampling reports that clindamycin appears in human breast milk in the range of less than 0.5 to 3.8 mcg/mL at dosages of 150 mg orally to 600 mg intravenously. Clindamycin has the potential to cause adverse effects on the breast-fed infant's gastrointestinal flora. If oral or intravenous clindamycin is required by a nursing mother, it is not a reason to discontinue breastfeeding, but an alternate drug may be preferred. Monitor the breast-fed infant for possible adverse effects on the gastrointestinal flora, such as diarrhea, candidiasis (thrush, diaper rash) or rarely, blood in the stool indicating possible antibiotic-associated colitis.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breast-fed child from clindamycin or from the underlying maternal condition.

Pediatric Use

When clindamycin Injection is administered to the pediatric population (birth to 16 years) appropriate monitoring of organ system functions is desirable (see **CLINICAL PHARMACOLOGY** and **DOSAGE AND ADMINISTRATION)**.

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 (see **WARNINGS).**

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 (see **WARNINGS)**.

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 *Clostridioides 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.

Infections and Infestations: *Clostridioides difficile* colitis

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 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.

Severe skin reactions such as Toxic Epidermal Necrolysis, some with fatal outcome, have been reported (see **WARNINGS**). Cases of Acute Generalized Exanthematous Pustulosis (AGEP), erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with clindamycin. Anaphylactic shock, anaphylactic reaction and hypersensitivity have also been reported (see **WARNINGS**).

Skin and Mucous Membranes: Pruritus, vaginitis, angioedema 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: Acute Kidney Injury: Signs of renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria have been observed (see **WARNINGS**).

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.

Immune System: Drug reaction with eosinophilia and systemic symptoms (DRESS) cases have been reported.

Local Reactions: Injection site irritation, 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: Polyarthritis cases have been reported.

Cardiovascular: 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).

Clindamycin phosphate IM administration should be used undiluted.

Clindamycin phosphate IV administration should be diluted (see **Dilution for IV use and IV infusion rates** below).

Adults

Parenteral (IM or IV 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*):

600–1200 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*:

1200–2700 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 for IV use and IV Infusion Rates** section below).

Single intramuscular 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 IV infusion as follows:

Table 2: Serum Clindamycin Levels Maintained, Rapid Infusion Rate and Maintenance Infusion Rate

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	1.00 mg/min
Above 6 mcg/mL	20 mg/min for 30 min	1.25 mg/min

Pediatric Patients 1 month of age to 16 years

Parenteral (IM or IV) Administration: 20 to 40 mg/kg/day in 3 or 4 equal doses. The higher doses would be used for more severe infections. Clindamycin should be dosed based on total body weight regardless of obesity. 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^2/day for serious infections and 450 mg/m^2/day for more severe infections.

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

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

Pediatric Patients less than 1 month

The recommended dosage is 15 to 20 mg/kg/day in 3 to 4 equal doses. See Table 3 regarding the dosing regimen for pediatric patients with post-menstrual age (PMA) less than or equal to 32 weeks, or greater than 32 weeks to less than or equal to 40 weeks.

Table 3: Dosing Regimens for Pediatric Patients with PMA less than or equal to 32 weeks, or greater than 32 weeks to less than or equal to 40 weeks

PMA (weeks)	Dose (mg/kg)	Dosing Interval (hours)
Less than or equal to 32	5	8
Greater than or equal to 32 to less than or equal to 40	7	8

PMA: Post-Menstrual age

Dilution for IV use and IV Infusion Rates

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 IV 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 Phosphate Room Temperature

6, 9 and 12 mg/mL (equivalent to clindamycin base) in dextrose injection 5%, sodium chloride injection 0.9%, or Lactated Ringers Injection in glass bottles or Mini-Bag containers, demonstrated physical and chemical stability for at least 16 days at 25°C. Also, 18 mg/mL (equivalent to clindamycin base) in dextrose injection 5%, in Mini-Bag containers, 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 dextrose injection 5%, sodium chloride injection 0.9%, or Lactated Ringers Injection in glass bottles or Mini-Bag containers, 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 dextrose injection 5%, sodium chloride injection 0.9%, or Lactated Ringers Injection in Mini-Bag containers demonstrated physical and chemical stability for at least eight weeks at -10°C.

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

DIRECTIONS FOR DISPENSING

Pharmacy Bulk Package — Not for Direct Infusion

The Pharmacy Bulk Package is for use in a Pharmacy Admixture Service only under a laminar flow hood. Entry into the vial should be made with a small diameter sterile transfer set or other small diameter sterile dispensing device, and contents dispensed in aliquots using aseptic technique. Multiple entries with a needle and syringe are not recommended. AFTER ENTRY USE ENTIRE CONTENTS OF VIAL PROMPTLY. ANY UNUSED PORTION MUST BE DISCARDED WITHIN 24 HOURS AFTER INITIAL ENTRY.

HOW SUPPLIED

Each mL of Clindamycin Injection, USP contains clindamycin phosphate equivalent to 150 mg clindamycin, 0.5 mg disodium edetate, 9.45 mg benzyl alcohol added as preservative. When necessary, pH is adjusted with sodium hydroxide and/or hydrochloric acid.

Clindamycin Injection, USP is supplied in single dose vials as follows:

NDC	Vial Size	Total Clindamycin Phosphate/vial
72611-634-25 (carton contains 25 vials of 72611-634-01)	2 mL	300 mg
72611-639-25 (carton contains 25 vials of 72611-639-01)	4 mL	600 mg
72611-642-25 (carton contains 25 vials of 72611-642-01)	6 mL	900 mg

Clindamycin Injection, USP is supplied as a Pharmacy Bulk Package as follows:

NDC	Vial Size	Total Clindamycin Phosphate/vial
72611-645-55 (carton contains 5 vials of 72611-645-11)	60 mL	9000 mg

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP].

REFERENCES

1. Smith RB, Phillips JP: Evaluation of CLEOCIN HCl and CLEOCIN Phosphate in an Aged Population. Upjohn TR 8147-82-9122-021, December 1982.

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Distributed by
Almaject Inc.
Morristown, NJ 07960 USA

Almaject®

LAB-1370-6.0
Revised: 10/2021

PRINCIPAL DISPLAY PANEL - 2 mL Vial Label

NDC 72611-634-01

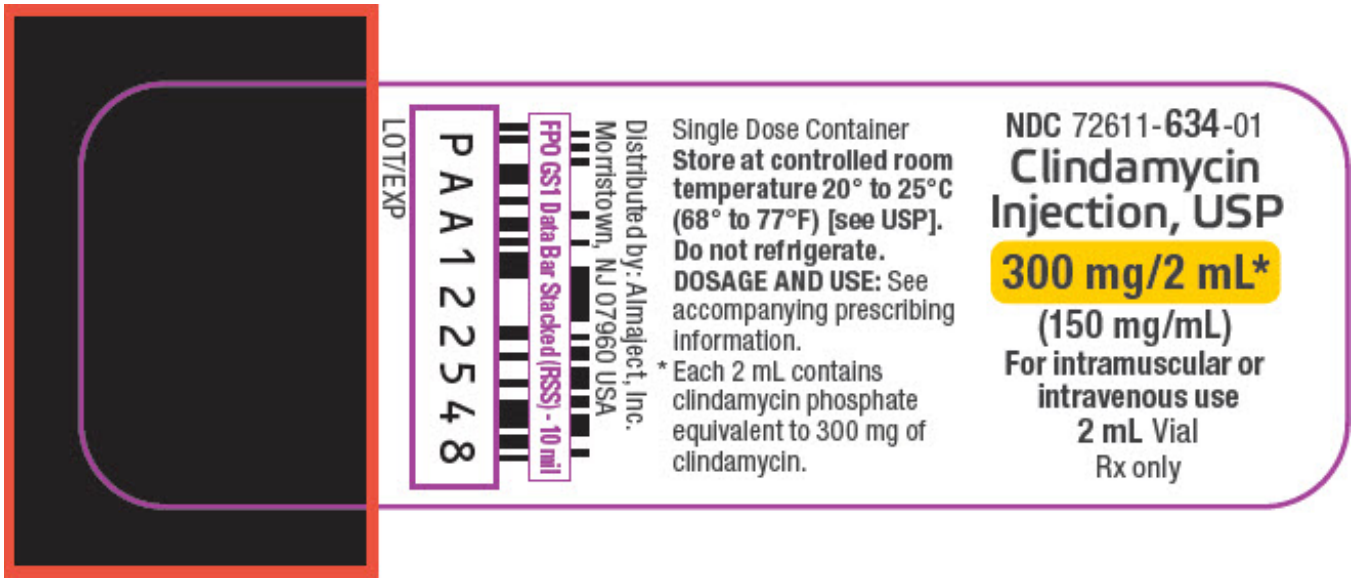
Clindamycin
Injection, USP

300 mg/2 mL*
(150 mg/mL)

For intramuscular or
intravenous use

2 mL Vial

Rx only



PRINCIPAL DISPLAY PANEL - 2 mL Vial Carton

25 x 2 mL Single-Dose Vials

NDC 72611-634-25
Contains 25 of NDC 72611-634-01

Clindamycin Injection, USP

300 mg/2 mL*
(150 mg/mL)

For intramuscular or intravenous use

Almaject®
Rx only

25 x **2 mL** Single-Dose Vials

NDC 72611-**634**-25
Contains 25 of NDC 72611-**634**-01

Clindamycin Injection, USP

300 mg/2 mL*

(150 mg/mL)

For intramuscular or intravenous use

Almaject®

Rx only

FPO UPC @ 80 %

N 3 7261-1634-25 8

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Morristown, NJ 07960 USA

Product of China

FPO 128 - 10 MIL
PAA142141

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LOT/EXP/SN:

GTIN: 00372611634258

Almaject®

25 x 2 mL Single-Dose Vials

Clindamycin Injection, USP

300 mg/2 mL*

(150 mg/mL)

For intramuscular or intravenous use

PAA142141

25 x **2 mL** Single-Dose Vials

Clindamycin Injection, USP

300 mg/2 mL*

(150 mg/mL)

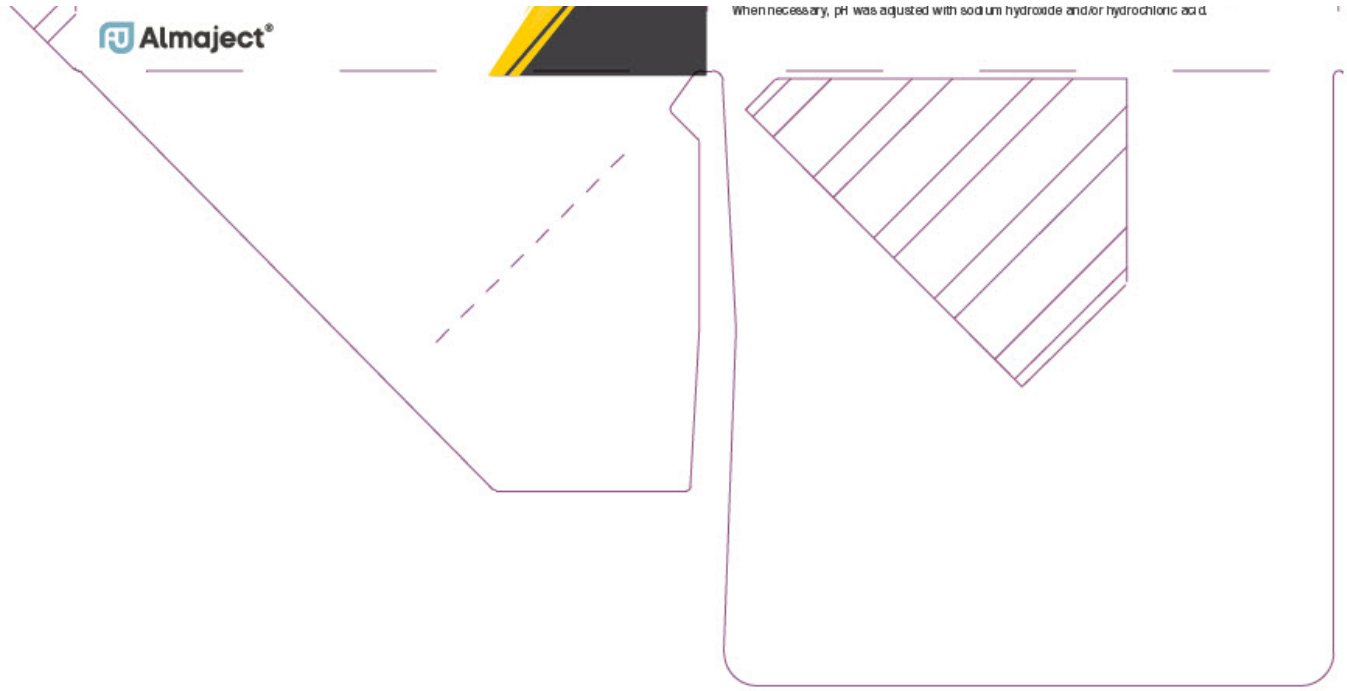
For intramuscular or intravenous use

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Do not refrigerate.

DOSAGE AND USE:
See accompanying prescribing information.

Warning—If given intravenously, must be diluted before use.

* Each 2 mL contains clindamycin phosphate equivalent to 300 mg of clindamycin.
Also contains disodium edetate, 1.0 mg; benzyl alcohol added as preservative, 18.9 mg.



PRINCIPAL DISPLAY PANEL - 4 mL Vial Label

NDC 72611-639-01

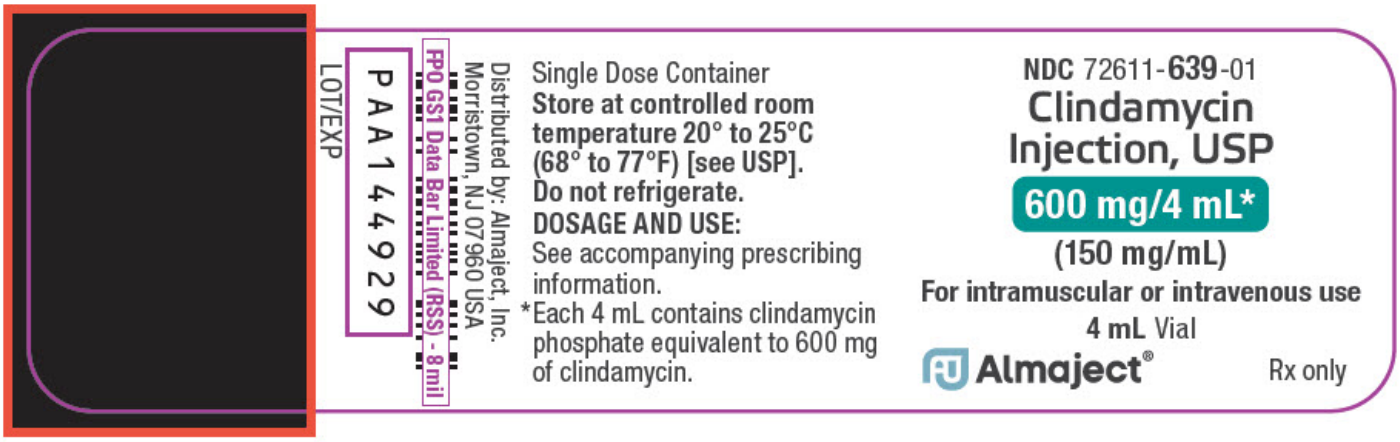
Clindamycin
Injection, USP

600 mg/4 mL*
(150 mg/mL)

For intramuscular or intravenous use

4 mL Vial

Almaject®
Rx only



PRINCIPAL DISPLAY PANEL - 4 mL Vial Carton

25 x 4 mL Single-Dose Vials

NDC 72611-639-25
Contains 25 of NDC 72611-639-01

Clindamycin Injection, USP

600 mg/4 mL*
(150 mg/mL)

For intramuscular or intravenous use

Almaject®
Rx only

25 x 4 mL Single-Dose Vials

NDC 72611-639-25
Contains 25 of NDC 72611-639-01

Clindamycin Injection, USP

600 mg/4 mL*

(150 mg/mL)

For intramuscular or intravenous use

Almaject®

Rx only

FPO UPC @ 100%

N 3 7261-1639-25 3

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FPO 72-10 MIL
PAA142142

LOT/EXP/SN:

GTIN: 00372611639253

Almaject®

Clindamycin Injection, USP

600 mg/4 mL*

(150 mg/mL)

For intramuscular or intravenous use

25 x 4 mL Single-Dose Vials

PAA142142

25 x 4 mL Single-Dose Vials

Clindamycin Injection, USP

600 mg/4 mL*

(150 mg/mL)

For intramuscular or intravenous use

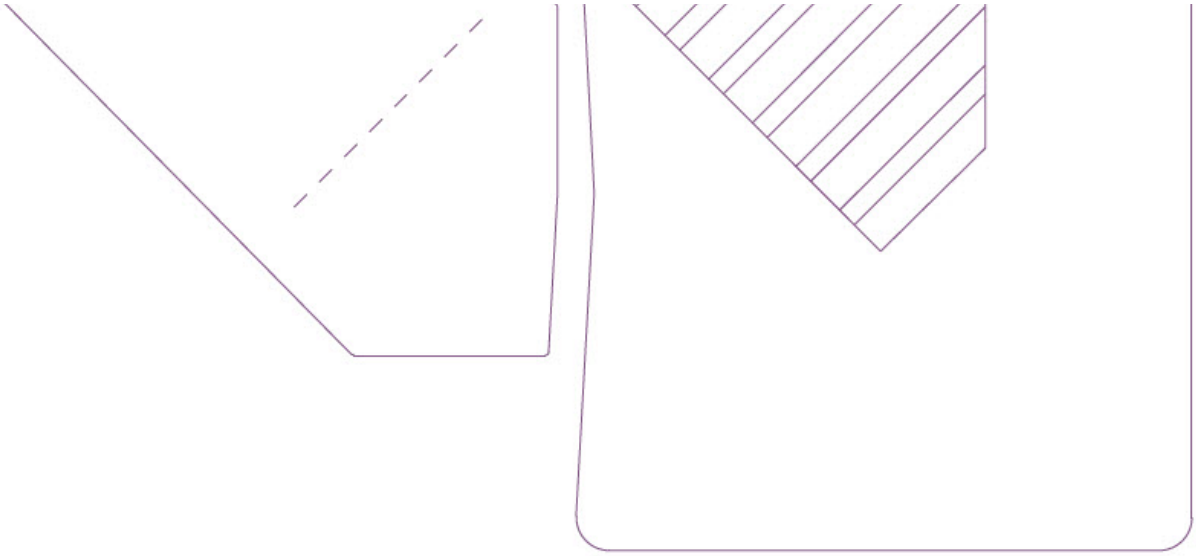
Almaject®

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Do not refrigerate.

DOSAGE AND USE:
See accompanying prescribing information.

Warning — If given intravenously, must be diluted before use.

*Each 4 mL contains clindamycin phosphate equivalent to 600 mg of clindamycin.
Also contains disodium edetate, 2.0 mg; benzyl alcohol added as preservative, 37.8 mg.
When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.



PRINCIPAL DISPLAY PANEL - 6 mL Vial Label

NDC 72611-642-01

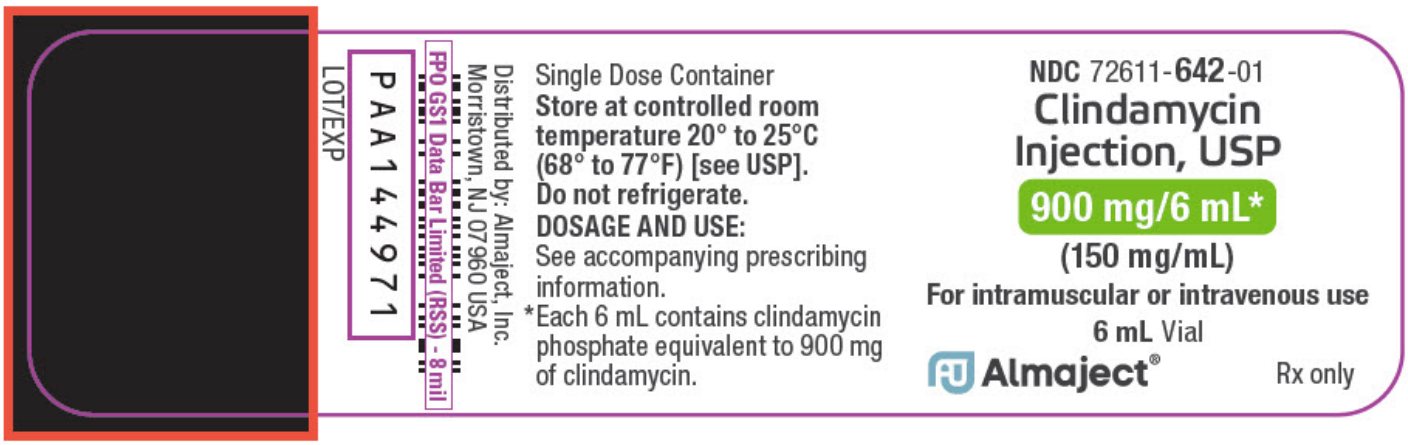
Clindamycin
Injection, USP

900 mg/6 mL*
(150 mg/mL)

For intramuscular or intravenous use

6 mL Vial

Almaject®
Rx only



PRINCIPAL DISPLAY PANEL - 6 mL Vial Carton

25 x 6 mL Single-Dose Vials

NDC 72611-642-25
Contains 25 of NDC 72611-642- 01

Clindamycin Injection, USP

900 mg/6 mL*
(150 mg/mL)

For intramuscular or intravenous use

Almaject®
Rx only

25 x 6 mL Single-Dose Vials

NDC 72611-642-25
Contains 25 of NDC 72611-642-01

Clindamycin Injection, USP

900 mg/6 mL*

(150 mg/mL)

For intramuscular or intravenous use

Almaject®

Rx only

FPO UPC @ 100 %

N 3 7261-1642-25 3

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FPO TZE - 10 MIL
PAA142143

LOT/EXP/S.N.:

GTIN: 00372616425 3

25 x 6 mL Single-Dose Vials

Clindamycin Injection, USP

900 mg/6 mL*

(150 mg/mL)

For intramuscular or intravenous use

Almaject®

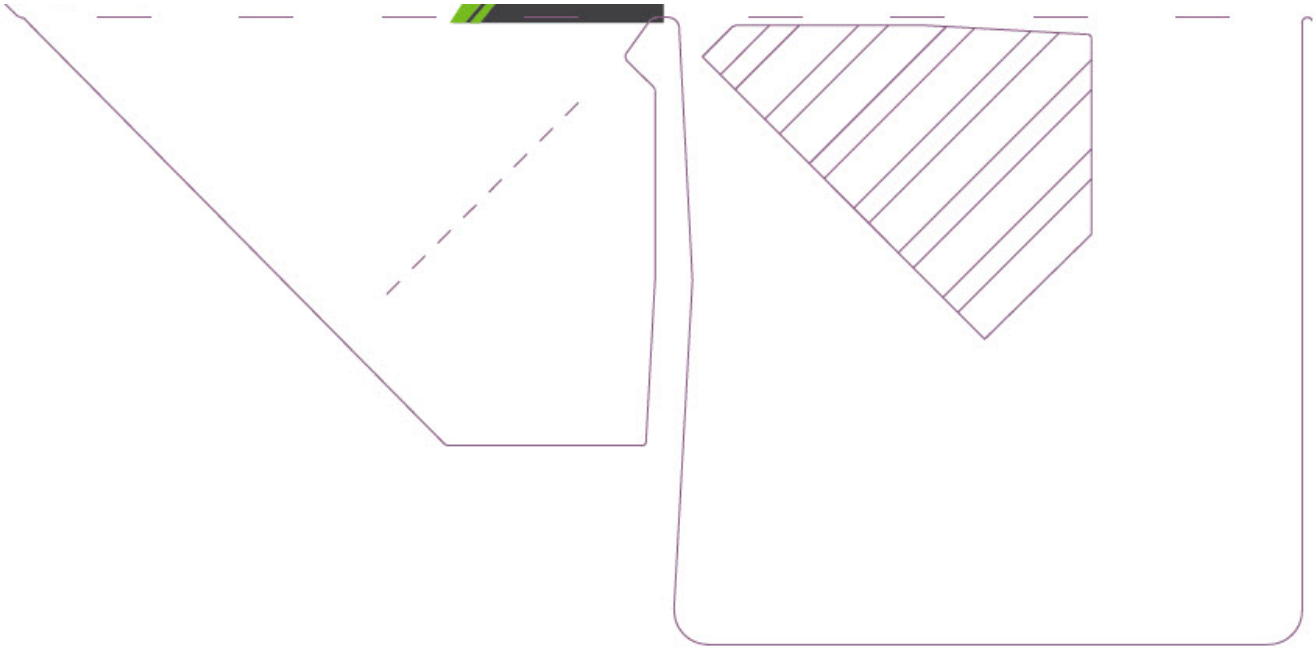
PAA 142143

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Do not refrigerate.

DOSAGE AND USE:
See accompanying prescribing information.

Warning—If given intravenously, must be diluted before use.

*Each 6 mL contains clindamycin phosphate equivalent to 900 mg of clindamycin.
Also contains disodium edetate, 3.0 mg; benzyl alcohol added as preservative, 56.7 mg.
When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.



PRINCIPAL DISPLAY PANEL - 60 mL Vial Label

NDC 72611-645-11

Clindamycin
Injection, USP

9,000 mg/60 mL*
(150 mg/mL)

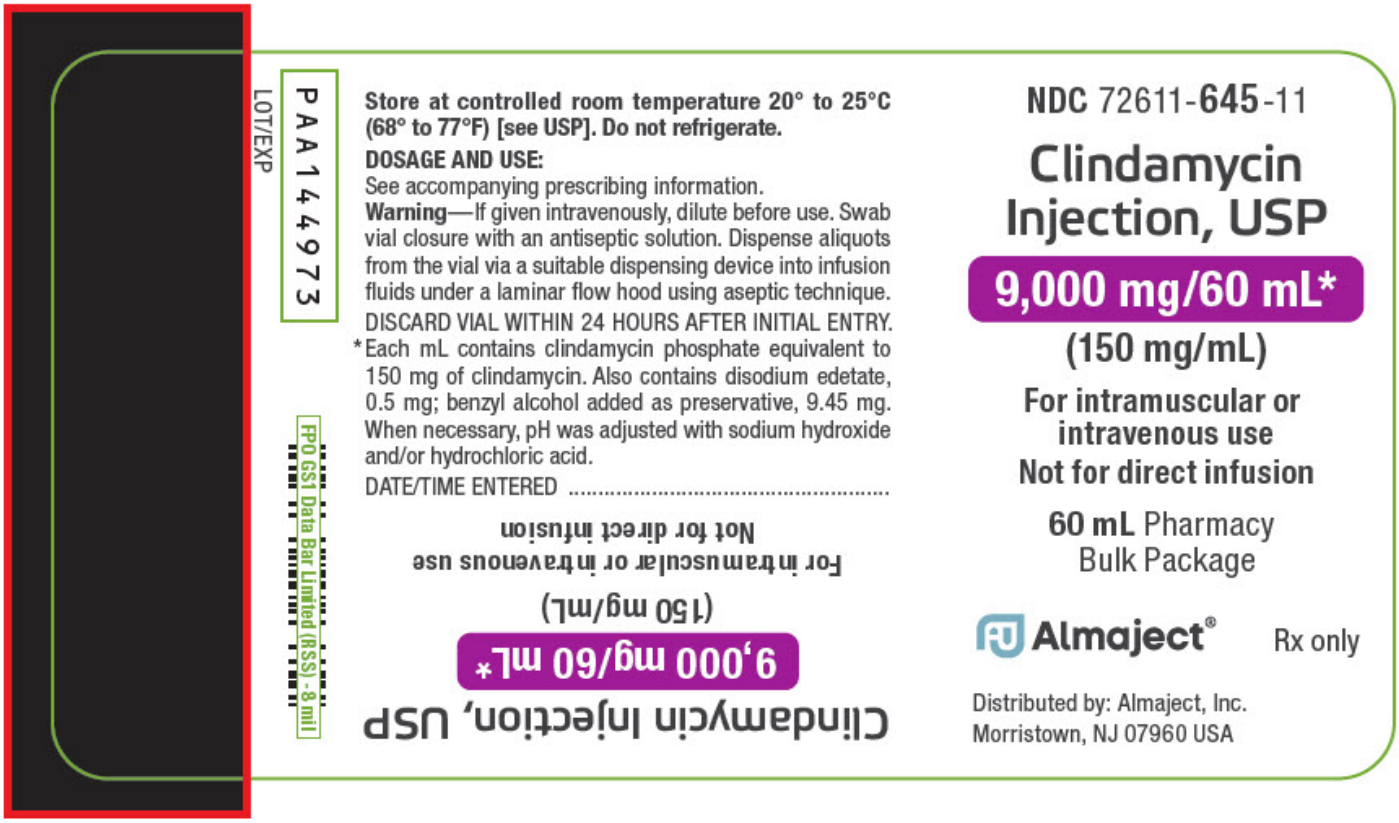
For intramuscular or
intravenous use

Not for direct infusion

60 mL Pharmacy
Bulk Package

Almaject®
Rx only

Distributed by: Almaject, Inc.
Morristown, NJ 07960 USA



PRINCIPAL DISPLAY PANEL - 60 mL Vial Carton

5 x 60 mL Pharmacy Bulk Packages

NDC 72611-645-55
Contains 5 of NDC 72611-645-11

Clindamycin Injection, USP

9,000 mg/60 mL*
(150 mg/mL)

For intramuscular or intravenous use
Not for direct infusion

Almaject®
Rx only

5 x 60 mL Pharmacy Bulk Packages

NDC 72611-645-55
Contains 5 of NDC 72611-645-11

Clindamycin Injection, USP

9,000 mg/60 mL*

(150 mg/mL)

For intramuscular or intravenous use
Not for direct infusion

Almaject®

Rx only

FPO UPC @ 100 %

N 3 7261-1645-55 1

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Almaject, Inc.
Morristown, NJ 07960 USA

Product of China

PAA142144

Store at controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Do not refrigerate.

DOSAGE AND USE:
See accompanying prescribing information

5 x 60 mL Pharmacy Bulk Packages

Clindamycin Injection, USP

LOT:
EXP:
SN:

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NO INK

GTIN: 00372816456561

5 x 60 mL Pharmacy Bulk Packages

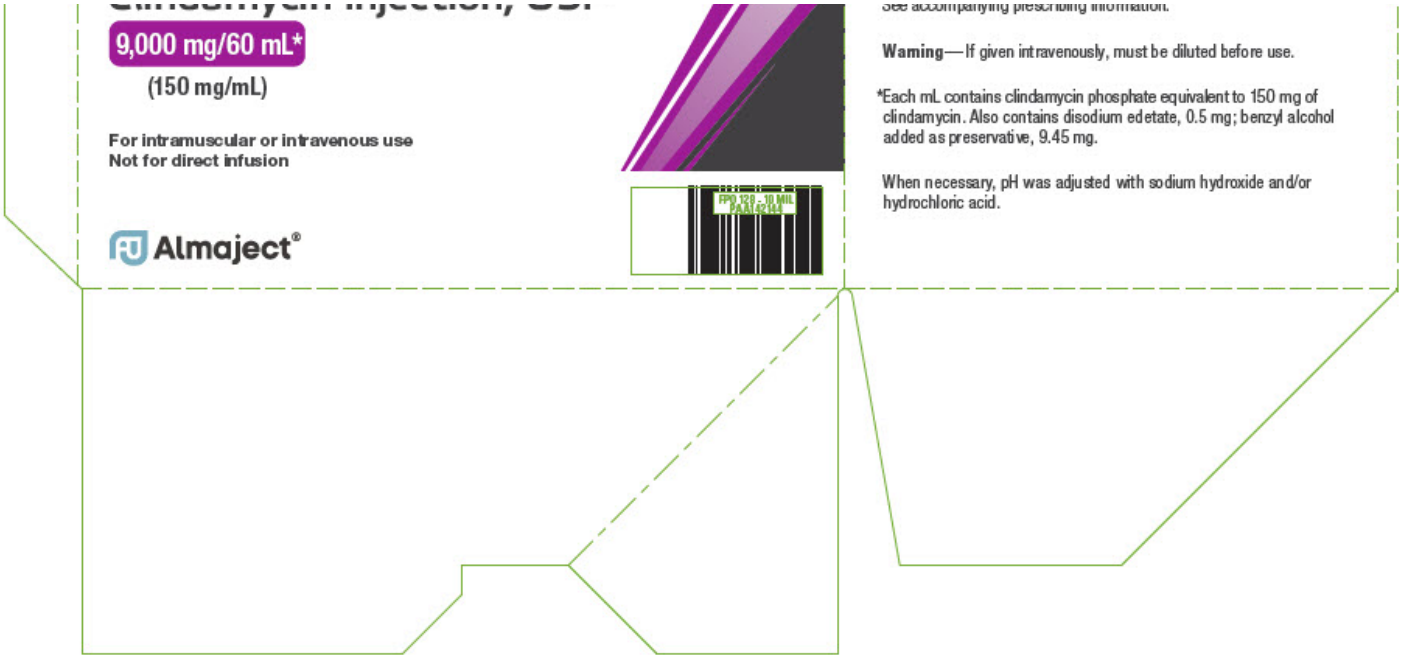
Clindamycin Injection, USP

9,000 mg/60 mL*

(150 mg/mL)

For intramuscular or intravenous use
Not for direct infusion

Almaject®



CLINDAMYCIN PHOSPHATE

clindamycin phosphate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72611-634
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	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:72611-634-25	25 in 1 CARTON	06/30/2019	
1	NDC:72611-634-01	2 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050441	10/02/1972	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72611-639
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	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:72611-639-25	25 in 1 CARTON	06/30/2019	
1	NDC:72611-639-01	4 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050441	10/02/1972	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72611-642
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	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:72611-642-25	25 in 1 CARTON	06/30/2019	
1	NDC:72611-642-01	6 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050441	10/02/1972	

CLINDAMYCIN PHOSPHATE

clindamycin phosphate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72611-645
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN PHOSPHATE (UNII: EH6D7113I8) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	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:72611-645-55	5 in 1 CARTON	06/30/2019	
1	NDC:72611-645-11	60 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA050441	10/02/1972	

Labeler - ALMAJECT, INC. (116626205)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(72611-634, 72611-639, 72611-642, 72611-645) , MANUFACTURE(72611-634, 72611-639, 72611-642, 72611-645) , API MANUFACTURE(72611-634, 72611-639, 72611-642, 72611-645) , PACK(72611-634, 72611-639, 72611-642, 72611-645) , LABEL(72611-634, 72611-639, 72611-642, 72611-645)

Revised: 10/2021 ALMAJECT, INC.