

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208083Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CLINDAMYCIN IN 0.9% SODIUM CHLORIDE injection safely and effectively. See full prescribing information for CLINDAMYCIN IN 0.9% SODIUM CHLORIDE injection.

CLINDAMYCIN IN 0.9% SODIUM CHLORIDE injection, for intravenous use

Initial U.S. Approval: 1989

WARNING: *CLOSTRIDIUM DIFFICILE*-ASSOCIATED DIARRHEA (CDAD) and COLITIS

See full prescribing information for complete boxed warning.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Clindamycin in 0.9% Sodium Chloride Injection 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* (5.1).

Because Clindamycin in 0.9% Sodium Chloride Injection 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 (1). 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 (5.1).

INDICATIONS AND USAGE

Clindamycin is a lincosamide antibacterial indicated for the treatment of the following:

- Serious infections caused by susceptible anaerobic bacteria (1.1)
- Infections Due to Susceptible Strains of Streptococci, Pneumococci and Staphylococci. (1.2)
- Lower Respiratory Tract Infections. (1.3)
- Skin and Skin Structure Infections. (1.4)
- Gynecological Infections. (1.5)
- Intra-abdominal Infections. (1.6)
- Septicemia. (1.7)
- Bone and Joint Infections. (1.8)

Limitation of use

Since clindamycin does not diffuse adequately into the cerebrospinal fluid, Clindamycin in 0.9% Sodium Chloride Injection should not be used in the treatment of meningitis (1.9)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Clindamycin in 0.9% Sodium Chloride Injection and other antibacterial drugs, Clindamycin in 0.9% Sodium Chloride Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. (1.10)

DOSAGE AND ADMINISTRATION

- Recommended Adult Dosage: 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 by intravenous infusion. (2.2)
- 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 by intravenous infusion. (2.2)

- Dosage in Pediatric Patients (1 Month of Age to 16 Years): 20 to 40 mg/kg/day in 3 or 4 equal doses by intravenous infusion. (2.3)
- Alternative Pediatric Patients Dosing: 350 mg/m²/day for serious infections and 450 mg/m²/day for more severe infections. (2.3)
- Dosage in Neonates (Less than 1 Month of Age): 15 to 20 mg/kg/day in 3 to 4 equal doses by intravenous infusion. (2.4)

DOSAGE FORMS AND STRENGTHS

Each 50 mL of Clindamycin in 0.9% Sodium Chloride Injection, 300 mg/50 mL (6 mg/mL), 600 mg/50 mL (12 mg/mL), and 900 mg/50 mL (18 mg/mL) contains 300 mg, 600 mg, or 900 mg clindamycin, respectively (as clindamycin phosphate, USP), in a single-dose GALAXY container. (3)

CONTRAINDICATIONS

Individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin. (4)

WARNINGS AND PRECAUTIONS

- Anaphylactic shock and anaphylactic reactions have been reported. (5.2)
- Elderly patients with associated severe illness may have a greater risk of developing adverse reactions from diarrhea. (5.3)
- Clindamycin in 0.9% Sodium Chloride Injection products should be avoided in individuals with a history of gastrointestinal disease, particularly colitis. (5.4)
- Clindamycin in 0.9% Sodium Chloride Injection should be avoided in atopic individuals. (5.5)
- During prolonged therapy periodic liver and kidney function tests and blood counts should be performed. (5.6)
- The use of Clindamycin in 0.9% Sodium Chloride Injection may result in overgrowth of nonsusceptible organisms—particularly yeasts. (5.7)
- Prescribing Clindamycin in 0.9% Sodium Chloride Injection 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. (5.8)

ADVERSE REACTIONS

Most common adverse reactions: gastrointestinal (abdominal pain, nausea, vomiting) and hypersensitivity reactions (anaphylaxis, urticaria, skin rash). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Celerity Pharmaceuticals, LLC at 1-855-669-0600 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. (7)
- Antagonism has been demonstrated between clindamycin and erythromycin. (7)

USE IN SPECIFIC POPULATIONS

- Pediatric Use: Appropriate monitoring of organ system functions is desirable. (8.4)
- Geriatric Use: Monitor for development of diarrhea. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 4/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: *CLOSTRIDIUM DIFFICILE*-ASSOCIATED DIARRHEA (CDAD) and COLITIS

1 INDICATIONS AND USAGE

- 1.1 Infections Due to Susceptible Anaerobic Bacteria
- 1.2 Infections Due to Susceptible Strains of Streptococci, Pneumococci and Staphylococci
- 1.3 Lower Respiratory Tract Infections
- 1.4 Skin and Skin Structure Infections
- 1.5 Gynecological Infections
- 1.6 Intra-abdominal Infections
- 1.7 Septicemia
- 1.8 Bone and Joint Infections
- 1.9 Limitations of Use
- 1.10 Usage

2 DOSAGE AND ADMINISTRATION

- 2.1 Important Discontinuation Instructions
- 2.2 Recommended Adult Dosage
- 2.3 Dosage in Pediatric Patients (1 Month of Age to 16 Years)
- 2.4 Dosage in Pediatric Patients (Neonates Less than 1 Month)
- 2.5 Intravenous Infusion Rates
- 2.6 Directions for Use of Clindamycin in 0.9% Sodium Chloride Injection in GALAXY Plastic Container

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 *Clostridium difficile* Associated Diarrhea
- 5.2 Anaphylactic and Severe Hypersensitivity Reactions
- 5.3 Diarrhea in Elderly Patients with Associated Severe Illness

- 5.4 Use in Patients with Gastrointestinal Disease
- 5.5 Use in Atopic Individuals
- 5.6 Laboratory Tests: Monitoring to Assess Safety
- 5.7 Overgrowth of Nonsusceptible Organisms
- 5.8 Development of Drug-Resistant Bacteria

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.3 Pharmacokinetics
- 12.4 Microbiology

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: *CLOSTRIDIUM DIFFICILE*-ASSOCIATED DIARRHEA (CDAD) and COLITIS

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Clindamycin in 0.9% Sodium Chloride Injection 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 in 0.9% Sodium Chloride Injection 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 [see *Indications and Usage (1)*]. 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 antibacterial 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 antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated. [see *Warnings and Precautions (5.1)*]

1 INDICATIONS AND USAGE

1.1 Infections Due to Susceptible Anaerobic Bacteria

Clindamycin in 0.9% Sodium Chloride Injection is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria [see *Indications and Usage (1.3 - 1.7)*].

1.2 Infections Due to Susceptible Strains of Streptococci, Pneumococci and Staphylococci

Clindamycin in 0.9% Sodium Chloride Injection is indicated for 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 antibacterial-associated pseudomembranous colitis, [see *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 antibacterial therapy.

1.3 Lower Respiratory Tract Infections

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious lower respiratory tract infections including pneumonia, empyema, and lung abscess caused by susceptible strains of anaerobes, *Streptococcus pneumoniae*, other streptococci (except *E. faecalis*), and *Staphylococcus aureus*.

1.4 Skin and Skin Structure Infections

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious skin and skin structure infections caused by susceptible strains of *Streptococcus pyogenes*, *Staphylococcus aureus*, and anaerobes.

1.5 Gynecological Infections

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious gynecological infections including endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis, and postsurgical vaginal cuff infection caused by susceptible anaerobes.

1.6 Intra-abdominal Infections

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious intra-abdominal infections including peritonitis and intra-abdominal abscess caused by susceptible anaerobic organisms.

1.7 Septicemia

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious septicemia caused by susceptible strains of *Staphylococcus aureus*, streptococci (except *Enterococcus faecalis*), and susceptible anaerobes.

1.8 Bone and Joint Infections

Clindamycin in 0.9% Sodium Chloride Injection is indicated in the treatment of serious bone and joint infections including acute hematogenous osteomyelitis caused by susceptible strains of *Staphylococcus aureus* and as adjunctive therapy in the surgical treatment of chronic bone and joint infections due to susceptible organisms.

1.9 Limitations of Use

Since clindamycin does not diffuse adequately into the cerebrospinal fluid, Clindamycin in 0.9% Sodium Chloride Injection should not be used in the treatment of meningitis [*see Clinical Pharmacology (12.3)*].

1.10 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Clindamycin in 0.9% Sodium Chloride Injection and other antibacterial drugs, Clindamycin in 0.9% Sodium Chloride Injection 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.

2 DOSAGE AND ADMINISTRATION

2.1 Important Discontinuation Instructions

Discontinue Clindamycin in 0.9% Sodium Chloride Injection if diarrhea occurs during therapy [see *Boxed Warning*].

2.2 Recommended Adult Dosage

The recommended dosing regimen for Clindamycin in 0.9% Sodium Chloride Injection is 600-1200 mg/day in 2, 3, or 4 equal doses by intravenous infusion for 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*).

For more severe infections, particularly those due to proven or suspected *Bacteroides fragilis*, *Peptococcus* species, or *Clostridium* species other than *Clostridium perfringens*, the recommended dosing regimen is 1200-2700 mg/day in 2, 3, or 4 equal doses by intravenous infusion.

In life-threatening situations, these doses may be increased. Doses of as much as 4800 mg daily have been given intravenously to adults [see *Dosage and Administration (2.4)*].

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

Table 1: Infusion Rates for the Administration of Clindamycin Injection by Single Rapid Infusion followed by Continuous Intravenous Infusion

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

2.3 Dosage in Pediatric Patients (1 Month of Age to 16 Years)

The recommended dosing regimen for pediatric patients is 20 to 40 mg/kg/day in 3 or 4 equal doses by intravenous infusion. 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/m²/day for serious infections and 450 mg/m²/day for more severe infections.

Parenteral therapy may be changed to oral clindamycin palmitate hydrochloride powder for oral solution 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.

2.4 Dosage in Pediatric Patients (Neonates Less than 1 Month)

The recommended dosing regimen for neonates is 15 to 20 mg/kg/day in 3 to 4 equal doses by intravenous infusion. The lower dosage may be adequate for small prematures.

2.5 Intravenous Infusion Rates

Infusion rates should **NOT** exceed 30 mg per minute. The usual infusion rates are as follows:

Dose	Time
300 mg	10 min
600 mg	20 min
900 mg	30 min

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

2.6 Directions for Use of Clindamycin in 0.9% Sodium Chloride Injection in GALAXY Plastic Container

Premixed Clindamycin in 0.9% Sodium Chloride Injection is for intravenous infusion using sterile equipment. Check for minute leaks prior to use by squeezing bag firmly. If leaks are found, discard solution as sterility may be impaired. Do **NOT** add supplementary medication. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do **NOT** use unless solution is clear and seal is intact.

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.

Preparation for Administration:

1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

3 DOSAGE FORMS AND STRENGTHS

Injection: Sterile, clear and colorless solution available in three strengths:

- 300 mg/50 mL (6 mg/mL): Each 50 mL single-dose GALAXY container contains 300 mg clindamycin (as clindamycin phosphate, USP) in 0.9% sodium chloride.
- 600 mg/50 mL (12 mg/mL): Each 50 mL single-dose GALAXY container contains 600 mg clindamycin (as clindamycin phosphate, USP) in 0.9% sodium chloride.
- 900 mg/50 mL (18 mg/mL): Each 50 mL single-dose GALAXY container contains 900 mg clindamycin (as clindamycin phosphate, USP) in 0.9% sodium chloride.

4 CONTRAINDICATIONS

Clindamycin in 0.9 % Sodium Chloride Injection is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

5 WARNINGS AND PRECAUTIONS

5.1 *Clostridium difficile* Associated Diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Clindamycin in 0.9% Sodium Chloride Injection, 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 antibacterial 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 antibacterial use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated [see *Boxed Warning*].

5.2 Anaphylactic and Severe Hypersensitivity Reactions

Anaphylactic shock and anaphylactic reactions have been reported [see *Adverse Reactions (6)*]. 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 (6)*].

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.

5.3 Diarrhea in Elderly Patients with Associated Severe Illness

Elderly patients with associated severe illness may have a greater risk of developing adverse reactions from diarrhea. When clindamycin is indicated in these patients, they should be carefully monitored for change in bowel frequency.

5.4 Use in Patients with Gastrointestinal Disease

Clindamycin in 0.9% Sodium Chloride Injection products should be avoided in individuals with a history of gastrointestinal disease, particularly colitis.

5.5 Use in Atopic Individuals

Clindamycin in 0.9% Sodium Chloride Injection should be avoided in atopic individuals.

5.6 Laboratory Tests: Monitoring to Assess Safety

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

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.

5.7 Overgrowth of Nonsusceptible Organisms

The use of Clindamycin in 0.9% Sodium Chloride Injection may result in overgrowth of nonsusceptible organisms-particularly yeasts. If such infections occur, appropriate measures should be taken as indicated by the clinical situation.

5.8 Development of Drug-Resistant Bacteria

Prescribing Clindamycin in 0.9% Sodium Chloride Injection 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.

6 ADVERSE REACTIONS

The following serious adverse reactions to clindamycin are described below and elsewhere in the labeling:

- *Clostridium difficile* Associated Diarrhea [*see Warnings and Precautions (5.1)*]
- Anaphylactic and Severe Hypersensitivity Reactions [*see Warnings and Precautions (5.2)*]

The following adverse reactions associated with the use of clindamycin were identified in clinical trials or postmarketing reports. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably, or to establish a causal relationship to drug exposure.

Infections and Infestations

Clostridium difficile colitis

Gastrointestinal

Antibiotic-associated colitis [*see Warnings and Precautions (5.1)*], pseudomembranous colitis, abdominal pain, nausea, and vomiting. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment [*see Warnings and Precautions (5.1)*]. 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 and Precautions (5.2)*]. 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 and Precautions (5.2)*].

Skin and Mucous Membranes

Pruritus, vaginitis, angioedema and rare instances of exfoliative dermatitis have been reported [*see Warnings and Precautions (5.2)*].

Liver

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

Renal

Renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed.

Hematopoietic

Transient neutropenia (leukopenia) and eosinophilia have been reported. Reports of agranulocytosis and thrombocytopenia have been made.

Immune System

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

Local Reactions

Thrombophlebitis has been reported after intravenous infusion. Avoid 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 (2)*].

7 DRUG INTERACTIONS

Neuromuscular Blocking Agents

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

Erythromycin

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

In limited published 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 major birth defects.

The limited published data on use of clindamycin in pregnant women with exposure during the first trimester are insufficient to inform a drug-associated risk of pregnancy-related adverse outcomes [*see Data*]. In animal reproduction studies, no evidence of any adverse developmental outcomes was observed when oral or subcutaneous doses of clindamycin were administered to pregnant rats and mice during organogenesis at doses half to twice the highest clinically relevant dose based on body surface area comparison [*see Data*]. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population,

the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Human Data

In limited published trials in pregnant women administered clindamycin during the first trimester of pregnancy, there was no difference in the rate of major birth defects reported among in utero exposed infants compared to unexposed infants. From these observational data, it is not possible to draw any conclusions on the rate of specific major birth defects associated with clindamycin. These data cannot definitely establish or exclude any clindamycin-associated risk during pregnancy.

Animal Data

Reproduction studies performed during organogenesis (gestational days 6-15) in pregnant rats and mice that were administered oral doses of clindamycin up to 600 mg/kg/day (twice or equivalent to the highest recommended adult human dose based on a body surface area comparison, respectively) or subcutaneous doses of clindamycin up to 250 mg/kg/day (equivalent to or half the highest recommended adult human dose based on a body surface area comparison, respectively) revealed no evidence of teratogenicity.

8.2 Lactation

Risk Summary

Clindamycin is present in breast milk in the range of 0.7 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 breastfed infant's gastrointestinal flora. There is no information on the effects of clindamycin on milk production. 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.

Clinical Considerations

Clindamycin may cause intestinal flora alteration. Advise a woman to monitor the breastfed infant for diarrhea, candidiasis (thrush, diaper rash) and bloody stools.

8.4 Pediatric Use

When Clindamycin in 0.9% Sodium Chloride Injection is administered to the pediatric population (birth to 16 years) appropriate dosing and monitoring of organ system functions is desirable.

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

8.5 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 antibacterial-associated colitis and diarrhea (due to *Clostridium difficile*) seen in association with most antibacterial drugs 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 [see *Clinical Pharmacology* (12.3)].

10 OVERDOSAGE

Significant mortality was observed in mice at an intravenous dose of 855 mg/kg (~3 times the human dose based on body surface area) and in rats at an oral or subcutaneous dose of approximately 2618 mg/kg (~18 times the human dose based on body surface area). In the mice, convulsions and depression were observed and in rats depression was observed prior to death.

Hemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

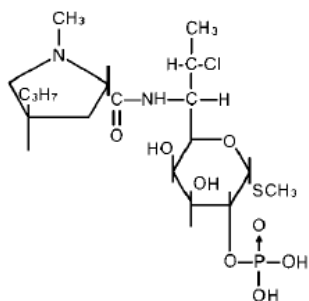
11 DESCRIPTION

Clindamycin is a lincosamide antibacterial and a semisynthetic drug 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-pyrrolidiny]carbonyl]amino]-1-thio-, 2-(dihydrogen phosphate), (*2S-trans*)-.

The molecular formula is C₁₈H₃₄ClN₂O₈PS and the molecular weight is 504.96.

The structural formula is represented below:



Clindamycin in 0.9% Sodium Chloride Injection is a clear, colorless and sterile solution for intravenous infusion. Each 50 mL Clindamycin in 0.9% Sodium Chloride Injection, 300 mg/50 mL, 600 mg/50 mL, and 900 mg/50 mL, contains 300 mg, 600 mg or 900 mg clindamycin, respectively (as clindamycin phosphate, USP), 450 mg of sodium chloride USP, 2 mg of edetate disodium dihydrate USP, and water for injection USP. The pH is adjusted with sodium hydroxide and /or hydrochloric acid. Clindamycin in 0.9% Sodium Chloride Injection is filled in GALAXY plastic container fabricated from a specially designed multilayer plastic, PL 2501. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period. The suitability of the plastic has been confirmed in tests in animals according to the USP biological tests for plastic containers, as well as by tissue culture toxicity studies.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Clindamycin is an antibacterial drug [see *Microbiology (12.4)*].

12.3 Pharmacokinetics

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

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 intravenous peak serum levels as given in Table 2 by application of elimination half-lives described in the elimination section below.

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.

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

Table 2. Average Peak and Trough Serum Concentrations of Active Clindamycin After Dosing with Clindamycin Phosphate

Dosage Regimen	Peak mcg/mL	Trough mcg/mL
Healthy Adult Males (Post equilibrium)		
600 mg IV in 30 min q6h	10.9	2.0
600 mg IV in 30 min q8h	10.8	1.1
900 mg IV in 30 min q8h	14.1	1.7
Pediatric Patients (first dose)*		
5–7 mg/kg IV in 1 hour	10	

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

Distribution

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

Elimination

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 2 ½ hours in pediatric patients.

Specific Populations

Patients with Renal 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 the presence of mild or moderate 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 intravenous administration of clindamycin phosphate. After oral administration of clindamycin hydrochloride, 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 function¹.

12.4 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 (1)*].

Aerobic bacteria

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible strains)

Streptococcus pneumoniae (penicillin-susceptible strains)

Streptococcus pyogenes

Anaerobic bacteria

Gram-positive bacteria

Clostridium perfringens

Peptostreptococcus anaerobius

Gram-negative bacteria

Fusobacterium necrophorum

Fusobacterium nucleatum

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 similar genus or organism group. However, the efficacy of clindamycin in treating clinical infections caused by these bacteria has not been established in adequate and well-controlled clinical trials.

Aerobic bacteria

Gram-positive bacteria

Staphylococcus epidermidis (methicillin-susceptible strains)

Streptococcus agalactiae

Streptococcus anginosus

Streptococcus mitis

Streptococcus oralis

Anaerobic bacteria

Gram-positive bacteria

Actinomyces israelii

Clostridium clostridioforme

Eggerthella lenta

Finegoldia (Peptostreptococcus) magna

Micromonas (Peptostreptococcus) micros

Propionibacterium acnes

Gram-negative bacteria

Prevotella bivia

Prevotella intermedia

Susceptibility Test Methods

When available, the clinical microbiology laboratory should provide cumulative reports of *in vitro* susceptibility test results for antimicrobial drugs used in local hospitals and practice areas as periodic reports that describe the susceptibility profile of nosocomial and community-acquired pathogens. These reports should aid in the selection of an appropriate antibacterial drug for treatment.

Dilution Techniques

Quantitative methods are used to determine antimicrobial MICs. These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized test method^{2,3} (broth and/or agar). The MIC values should be interpreted according to criteria provided in Table 3.

Diffusion Techniques

Quantitative methods that require the measurement of zone diameters can also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The zone size should be determined using a standardized test method^{2,5}. This procedure uses

paper disks impregnated with 2 mcg of clindamycin to test the susceptibility of bacteria to clindamycin. The disk diffusion breakpoints are provided in Table 3.

Anaerobic Techniques

For anaerobic bacteria, the susceptibility to clindamycin can be determined by a standardized test method^{2,4}. The MIC values obtained should be interpreted according to the criteria provided in Table 3.

Table 3. Susceptibility Test Interpretive Criteria for Clindamycin

Pathogen	Susceptibility Interpretive Criteria					
	Minimum Inhibitory Concentrations (mcg/mL)			Disk Diffusion (zone diameters in mm)		
	S	I	R	S	I	R
<i>Staphylococcus</i> spp.	≤ 0.5	1–2	≥ 4	≥ 21	15–20	≤ 14
<i>Streptococcus pneumoniae</i> and other <i>Streptococcus</i> spp.	≤ 0.25	0.5	≥ 1	≥ 19	16–18	≤ 15
Anaerobic Bacteria	≤ 2	4	≥ 8	NA	NA	NA

NA = not applicable

A report of *Susceptible (S)* indicates that the antimicrobial drug is likely to inhibit growth of the pathogen if the antimicrobial drug reaches the concentration usually achievable at the site of infection. A report of *Intermediate (I)* 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 (R)* indicates that the antimicrobial drug is not likely to inhibit growth of the pathogen if the antimicrobial drug reaches the concentration usually achievable at the infection site; 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^{2,3,4,5}. Standard clindamycin powder should provide the following range of MIC values noted in Table 4. For the diffusion technique using the 2 mcg clindamycin disk, the criteria in Table 3 should be achieved.

Table 4. Acceptable Quality Control Ranges for Clindamycin

QC Strain	Minimum Inhibitory Concentrations (mcg/mL)	Disk Diffusion (zone diameters in mm)
<i>Enterococcus faecalis</i> * ATCC 29212	4–16	NA
<i>Staphylococcus aureus</i> ATCC 29213	0.06–0.25	NA

<i>Staphylococcus aureus</i> ATCC 25923	NA	24–30
<i>Streptococcus pneumoniae</i> ATCC 49619	0.03–0.12	19–25
<i>Bacteroides fragilis</i> ATCC 25285	0.5–2	NA
<i>Bacteroides thetaiotaomicron</i> ATCC 29741	2–8	NA
<i>Clostridium difficile</i> [†] ATCC 700057	2–8	NA
<i>Eggerthella lenta</i> ATCC 43055	0.06–0.25	NA

NA=Not applicable

ATCC[®] is a registered trademark of the American Type Culture Collection

* *Enterococcus faecalis* has been included in this table for quality control purposes only.

† 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 dilution methods.

13 NONCLINICAL TOXICOLOGY

13.1 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/m²) revealed no effects on fertility or mating ability.

15 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.
2. CLSI. *Performance Standards for Antimicrobial Susceptibility Testing*: 27th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.
3. CLSI. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard - Tenth Edition*. CLSI document M07-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
4. CLSI. *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard-Eighth Edition*. CLSI document M11-A8. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.
5. CLSI. *Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - Twelfth Edition*. CLSI document M02-A12. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.

16 HOW SUPPLIED/STORAGE AND HANDLING

Clindamycin in 0.9% Sodium Chloride Injection for intravenous infusion. Each 50 mL of Clindamycin in 0.9% Sodium Chloride Injection, 300 mg/50 mL, 600 mg/50 mL, and 900 mg/50 mL, contains 300 mg, 600 mg or 900 mg clindamycin, respectively (as clindamycin phosphate, USP). Clindamycin in 0.9% Sodium Chloride Injection in single-dose GALAXY containers is available as follows:

2G3455	Twenty-four (24)-300 mg/50 mL containers	NDC 67798-306-24
2G3456	Twenty-four (24)-600 mg/50 mL containers	NDC 67798-612-24
2G3457	Twenty-four (24)-900 mg/50 mL containers	NDC 67798-918-24

Exposure of pharmaceutical products, including Clindamycin in 0.9 % Sodium Chloride, to heat should be minimized. It is recommended that GALAXY plastic containers be stored at 20°C to 25°C (68°F to 77°F) excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Avoid temperatures above 30°C.

17 PATIENT COUNSELING INFORMATION

- Counsel patients that antibacterial drugs including Clindamycin in 0.9% Sodium Chloride Injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Clindamycin in 0.9% Sodium Chloride Injection is prescribed to treat a bacterial infection, inform patient 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 in 0.9% Sodium Chloride Injection or other antibacterial drugs in the future.
- Counsel patients that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterial drugs, 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 antibacterial drugs. If this occurs, contact physician as soon as possible [*see Warnings and Precautions (5.4)*].
- Lactation: Advise a woman to monitor the breastfed infant for diarrhea and bloody stools [*see Use in Specific Populations (8.2)*].

Clindamycin in 0.9% Sodium Chloride Injection in the GALAXY plastic containers is manufactured for Celerity Pharmaceuticals, LLC, Rosemont, IL 60018 by Baxter Healthcare Corporation, Deerfield, IL 60015.

Galaxy is a registered trademark of Baxter International Inc.

Celerity Pharmaceuticals, LLC
Rosemont, IL 60018 USA
1-855-669-0600
www.celeritypharma.com

Made in USA.

1. PROPOSED 300 MG CONTAINER LABEL

LOT:
EXP:



NDC 67798-306-05

Clindamycin in 0.9% Sodium Chloride Injection

300 mg per 50 mL
(6 mg / mL)

50 mL Single Dose GALAXY Container
Discard unused portion
For Intravenous Infusion Only

Code 2G3455
Sterile Nonpyrogenic

↑
Front of
Container

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 300 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Rx only

Store at 20°C to 25°C (68°F to 77°F)[see USP Controlled Room Temperature]. Avoid temperatures above 30°C.

CELERTY
Pharmaceuticals, LLC

PL 2501 Plastic

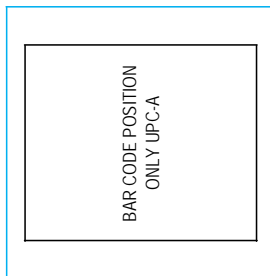
Manufactured for Celerity Pharmaceuticals, LLC
Rosemont, IL 60018 USA

Manufactured by Baxter Healthcare Corporation, Deerfield, IL 60015 USA

Galaxy is a registered trademark of Baxter International Inc.

Made in USA

↑
Back of
Container



2. PROPOSED 600 MG CONTAINER LABEL

LOT:
EXP:

NDC 67798-612-05

Clindamycin in 0.9% Sodium Chloride Injection

600 mg per 50 mL
(12 mg / mL)

GALAXY
50 mL Single Dose Container
Discard unused portion
For Intravenous Use

Code 2G3456
Sterile Nonpyrogenic

Not for rapid injection or Intravenous push

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 600 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Rx only

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

Avoid temperatures above 30°C.

CELERTY
Pharmaceuticals, LLC

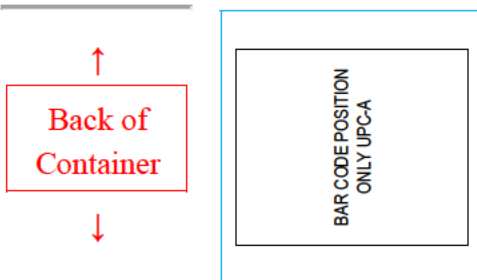
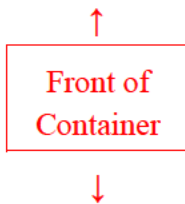
PL 2501 Plastic

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3. PROPOSED 900 MG CONTAINER LABEL

LOT:
EXP:



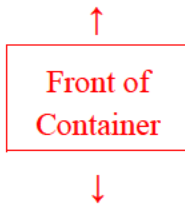
NDC 67798-918-05

Clindamycin in 0.9% Sodium Chloride Injection

900 mg per 50 mL
(18 mg / mL)

GALAXY
50 mL Single Dose Container
Discard unused portion
For Intravenous Use

Code 2G3457
Sterile Nonpyrogenic



Not for rapid injection or Intravenous push

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 900 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Rx only

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

Avoid temperatures above 30°C.

CELERTY
Pharmaceuticals, LLC

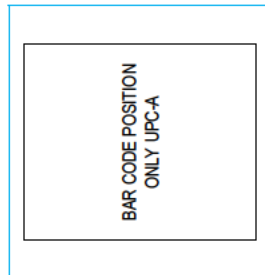
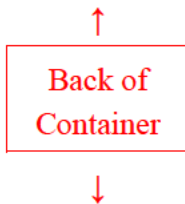
PL 2501 Plastic

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4. PROPOSED 300 MG CARTON LABEL

GALAXY Container

PL 2501 Plastic



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Manufactured by Baxter Healthcare Corporation, Deerfield, IL 60015 USA
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Left
Panel

Clindamycin in 0.9% Sodium Chloride Injection

Rx only

NDC 67798-306-24

Code 2G3455

300 mg per 50 mL (6 mg / mL)

Contains 12 - 50 mL Single Dose Containers

Store at 20°C to 25°C (68°F to 77°F)[see USP Controlled Room Temperature]. Avoid temperatures above 30°C.

*FOR BAR CODE POSITION ONLY

Center
Panel

(01) XXXXXXXXXXXXX

LOT

EXP

Sterile Nonpyrogenic

For Intravenous Infusion Only

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 300 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Right
Panel

5. PROPOSED 600 MG CARTON LABEL

GALAXY Container

PL 2501 Plastic



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Manufactured by Baxter Healthcare Corporation, Deerfield, IL 60015 USA
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Left
Panel

Clindamycin in 0.9% Sodium Chloride Injection
600 mg per 50 mL (12 mg / mL)

Rx only

NDC 67798-612-24
Code 2G3456

Contains 12 - 50 mL Single Dose Containers
Store at 20° to 25°C (68° to 77°F)[see USP Controlled
Room Temperature]. Avoid temperatures above 30°C.

*FOR BAR CODE POSITION ONLY

Center
Panel

(01) XXXXXXXXXXXXX

LOT

EXP

Sterile Nonpyrogenic

For Intravenous Use

Not for rapid injection or Intravenous push

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 600 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Cautions: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Right
Panel

6. PROPOSED 900 MG CARTON LABEL

GALAXY Container

PL 2501 Plastic



Manufactured for Celerity Pharmaceuticals, LLC, Rosemont, IL 60018 USA
Manufactured by Baxter Healthcare Corporation, Deerfield, IL 60015 USA
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Left
Panel

Clindamycin in 0.9% Sodium Chloride Injection

Rx only

NDC 67798-918-24

900 mg per 50 mL (18 mg / mL)

Code 2G3457

Contains 12 - 50 mL Single Dose Containers

Store at 20° to 25°C (68° to 77°F)[see USP Controlled Room Temperature]. Avoid temperatures above 30°C.

*FOR BAR CODE POSITION ONLY

Center
Panel

(01) XXXXXXXXXXXXX

LOT

EXP

Sterile Nonpyrogenic

For Intravenous Use

Not for rapid injection or Intravenous push

Each 50 mL contains: Clindamycin phosphate, USP equivalent to 900 mg clindamycin, 9 mg sodium chloride, USP, 2 mg edetate disodium dihydrate, USP, and Water for Injection, USP. pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Dosage: See prescribing information.

Caution: Do not add supplementary medication. Must not be used in series connections. Check for minute leaks and solution clarity.

Right
Panel

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/s/

SUMATHI NAMBIAR
04/20/2017