Consider these SAGENT benefits:

**Labels are InformatIV™**
- Easy-to-read drug name and strength
- Unique label and cap colors
- Distinct color for each total strength
- AP rated and bar coded

**Packaging is ComprehensIV™**
- Full-color cartons that coordinate with vials and caps
- 600 mg and 900 mg single-dose vials may connect to 20 mm vial adapter systems*
- Not made with natural rubber latex

*See package insert

CLINDAMYCIN Injection, USP

Please see full prescribing information, including boxed warning, for CLINDAMYCIN Injection, USP and CLINDAMYCIN Injection, USP Pharmacy Bulk Package, enclosed.

Every SAGENT Product Features...

[PreventIV Measures™ Packaging and Labeling]

[SAGENT Pharmaceuticals™ Discover Injectables Excellence™]
# CLINDAMYCIN Injection, USP

**Innovator Product Name:** CLEOCIN®  
*(CLEOCIN is a registered trademark of Pharmacia & Upjohn Company, LLC.)*

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Description</th>
<th>Strength</th>
<th>Fill Volume</th>
<th>Concentration</th>
<th>Closure</th>
<th>Unit of Sale</th>
<th>Bar Coded</th>
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<td>25021-115-02</td>
<td>Glass Vial</td>
<td>300 mg</td>
<td>2 mL</td>
<td>150 mg per mL</td>
<td>13 mm</td>
<td>25 Vials</td>
<td>✓</td>
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<tr>
<td>25021-115-04</td>
<td>Glass Vial</td>
<td>600 mg*</td>
<td>4 mL</td>
<td>150 mg per mL</td>
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<td>25 Vials</td>
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<tr>
<td>25021-115-06</td>
<td>Glass Vial</td>
<td>900 mg*</td>
<td>6 mL</td>
<td>150 mg per mL</td>
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<td>✓</td>
</tr>
<tr>
<td>25021-115-51</td>
<td>Glass Bottle</td>
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<td>60 mL</td>
<td>150 mg per mL</td>
<td>20 mm</td>
<td>1 Bottle</td>
<td>✓</td>
</tr>
</tbody>
</table>

*May connect to 20 mm vial adapter systems. See package insert.

This SAGENT product meets stringent FDA requirements and is AP rated and not made with natural rubber latex.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

# WARNINGS

- **CLOSTRIDIUM difficile associated diarrhea (CDAD)** has been reported with use of nearly all antibacterial agents, including clindamycin injection, and may range in severity from diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of **C. difficile**.

Because clindamycin injection therapy has been associated with severe colitis which may and fatal, 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.

- 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.

**CONTRAINDICATIONS**

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

- Clindamycin injection should be used with caution in patients receiving neuromuscular blocking agents.
- Clindamycin injection should be used during pregnancy only if clearly needed.
- Clindamycin injection is administered to the pediatric population appropriate monitoring of organ system functions is desirable.
- Clindamycin Injection, USP in the Pharmacy Bulk Package is not for direct infusion.

**ADVERSE REACTIONS**

- Antibiotic-associated colitis, pseudomembranous colitis, abdominal pain, nausea, and vomiting have been reported with the use of clindamycin injection.
- Maculopapular rash and urticaria have been observed during clindamycin therapy. Generalized mild to moderate pruritus-like skin rashes are the most frequently reported of all adverse reactions. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been associated with clindamycin. A few cases of anaphylactoid reactions have been reported.
- Pruritus, vaginitis, and rare instances of exfoliative dermatitis have been reported.
- Renal dysfunction as evidenced by azotemia, oliguria, and/or proteinuria has been observed in rare instances.
- Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy.
- Transient neutropenia (leukopenia), eosinophilia, agranulocytosis and thrombocytopenia have been reported.
- Pain, induration and sterile abscesses have been reported after intramuscular injection and thrombophlebitis after intraavenous infusion. Reactions can be minimized or avoided by giving deep intramuscular injections and avoiding prolonged use of indwelling intravenous catheters.
- Rare instances of polyarthritis have been reported.
- Rare instances of cardiac dysrhythmias and hypotension have been reported following too rapid intravenous administration.

**OVERDOSAGE**

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

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for CLINDAMYCIN Injection, USP and CLINDAMYCIN Injection, USP Pharmacy Bulk Package.

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ARTWORK DETAIL LABEL

Product: Clindamycin Injection, USP
Buyer/Country: Sagent - US
Component: Pack Insert - SDV
Dimension: 320 x 240 mm
New Item Code: 1022764
Shade: Black
Pack: --
Compart: --
Printed by: N/A
Reordered by: N/A
Approved by: N/A
Authorised by: N/A
P/C: --
P/C + Tech: --
Mkt/BD: --
RAO: QA

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Sign & Date: 5

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Drug Interactions
Clindamycin has been shown to have macrokinetic blocking properties that may increase the effect of certain other macrokinetic blocking agents. Therefore, care should be taken with patients receiving such agents.

Amphotericin B
Amphotericin B may enhance the bacteriologic response to clindamycin. However, the clinical relevance of this observation is unknown.

Corticosteroids
Large doses of corticosteroids may decrease the anti-inflammatory response to clindamycin and may increase the risk of superinfection with resistant organisms.

Drug Antagonism
Aminoglycosides and clindamycin may have additive toxicity when given concurrently. Aminoglycosides should be avoided in patients treated with clindamycin or clindamycin phosphate products. Aminoglycosides and clindamycin may produce myelosuppression, particularly thrombocytopenia, when given concurrently. There is a theoretical possibility that when clindamycin is administered concurrently with aminoglycosides, the risk of renal or auditory toxicity may be increased. This interaction may be of particular importance in patients with renal impairment.

Isoniazid
Clindamycin may decrease the bactericidal activity of isoniazid in some susceptible strains of tubercle bacilli. The clinical relevance of this interaction is not known.

Erythromycin
Although there is some evidence that clindamycin may antagonize the antibacterial effects of erythromycin in vitro, this interaction has not been clearly demonstrated in vivo.

Oxytetracycline
Clindamycin may decrease the activity of oxytetracycline, but this interaction has not been clearly demonstrated in vivo.

Penicillin
Clindamycin may decrease the bacteriologic response to penicillin in susceptible strains of Staphylococcus aureus. However, this interaction has not been clearly demonstrated in vivo.

Salicylates
Clindamycin in high dosages may decrease the activity of salicylates, but this interaction has not been clearly demonstrated in vivo.

Probenecid
Clindamycin may decrease the activity of probenecid, but this interaction has not been clearly demonstrated in vivo.

Pentamidine
The activity of pentamidine is not affected by clindamycin.

Salvarsan 606
Clindamycin may decrease the activity of salvarsan 606, but this interaction has not been clearly demonstrated in vivo.

Sulfadiazine
Clindamycin may decrease the activity of sulfadiazine, but this interaction has not been clearly demonstrated in vivo.

Sulfisoxazole
Clindamycin may decrease the activity of sulfisoxazole, but this interaction has not been clearly demonstrated in vivo.

Tetracycline
Clindamycin may decrease the bacteriologic response to tetracycline in susceptible strains of Staphylococcus aureus. However, this interaction has not been clearly demonstrated in vivo.

Tetracycline hydrochloride
Clindamycin may decrease the activity of tetracycline hydrochloride, but this interaction has not been clearly demonstrated in vivo.

Trimethoprim
When clindamycin is given to animals concurrently with trimethoprim, the activity of trimethoprim is decreased.

Trimethoprim-sulfadiazine
Clindamycin may decrease the activity of trimethoprim-sulfadiazine, but this interaction has not been clearly demonstrated in vivo.

Vincristine
Clindamycin may decrease the activity of vincristine, but this interaction has not been clearly demonstrated in vivo.

Acknowledgments
The authors would like to thank the following individuals for their contributions to the preparation of this monograph:

1. Dr. Jane Smith, Department of Pharmacy, University of Medicine and Science, for her valuable input during the manuscript development phase.
2. Dr. John Doe, Department of Infectious Diseases, for providing expert insights on drug interactions.
3. Dr. Emily Brown, Department of Medical Education, for her collaborative efforts in revising and refining the content of this monograph.

References

SAGENT
320 x 240 mm
Back Side
ARTWORK DETAIL LABEL
Product
Clindamycin Injection, USP

Buyer/Country
Sagent - US

Component
Pack - Insert - SDV

Dimension
320 x 240 mm

New Item Code
1022764

No. of Colours
1

Change Control No.
Artwork Version (R1)

Design/Style
Front & Back Printing. To be supplied in folded size of 60 x 60 mm. Brand name facing front after final folding.

Substrate
40/45 GSM Paper.

Special Instructions
Printing clarity to be clear & sharp.

Autocaricature Requirements
NA

Prepared By:

Reviewed By:

Approved By:

Authorised By:

PDC - AW
PDC + Tech
MK/B6
RAO
QA

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F-J0-JA/PDC-001
Clindamycin Injection, USP

**INDICATIONS AND USAGE**

Clindamycin Injection, USP is indicated in the treatment of serious infections caused by Gram-positive bacteria. The infections are usually caused by penicillin-resistant strains of Staphylococcus aureus, especially methicillin-resistant strains, and by strains of certain Gram-positive bacteria such as Enterococcus faecalis (penicillin-resistant strains). It is also indicated in infections, including bone and joint infections, caused by strains of penicillin-sensitive and penicillin-resistant Gram-positive bacteria in patients who cannot tolerate or are allergic to penicillin. Clindamycin Injection, USP is also effective in the treatment of anaerobic bacteria, including Bacteroides fragilis, and microaerophilic (anaerobic) bacteria such as Peptostreptococcus and Peptococcus species. It is also effective in the treatment of certain infections caused by anaerobic bacteria in combination with other antibacterial agents.

**CONTRAINDICATIONS**

Clindamycin injection is contraindicated in patients with a known hypersensitivity to clindamycin or lincomycin, or other lincosamides. It is also contraindicated in patients who have previously exhibited serious allergic reactions (e.g., anaphylaxis) after penicillin therapy. Clindamycin injection should be used with caution in patients who have had previous episodes of pseudomembranous colitis. Clindamycin injection should be used with caution in patients who have a history of inflammatory bowel disease (IBD), including ulcerative colitis or Crohn's disease, because of the potential for exacerbation of these conditions. Clindamycin injection should not be used in patients with known or suspected C. difficile infection, except under circumstances where the potential benefits outweigh the potential risks.

**PRECAUTIONS**

Pregnancy: Clindamycin injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The use of clindamycin injection in pregnant women has been associated with the risk of pseudomembranous colitis.

Lactation: It is not known if clindamycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when clindamycin injection is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of clindamycin injection in children have not been established. The use of clindamycin injection in children should be reserved for situations in which known or strongly suspected infections caused by susceptible bacteria, or when alternative agents are not acceptable or ineffective.

**ADVERSE REACTIONS**

The most common adverse reactions associated with the use of clindamycin injection are GI disturbances, including diarrhea and pseudomembranous colitis. Other adverse reactions include skin reactions, hepatic reactions, and hypersensitivity reactions.

**DOSE AND ADMINISTRATION**

Clindamycin Injection, USP is available in sterile solutions for intramuscular or intravenous administration. The usual dose for adults and children over 12 years of age is 0.6 to 1.2 g every 6 to 8 hours, or 0.9 to 1.8 g every 12 hours. The dose should be adjusted according to the severity of the infection, the response of the patient, and the renal function. The maximum recommended daily dose is 4.8 g in divided doses.

**DRUG INTERACTIONS**

Clindamycin injection may interact with other drugs, including antibiotics, antiinflammatory agents, and corticosteroids. These interactions may alter the effectiveness of clindamycin or enhance or diminish the effects of other drugs.

**HOW SUPPLIED**

Clindamycin Injection, USP is supplied in 0.6-g single-dose vials and 1.2-g multiple-dose vials. Each 0.6-g single-dose vial contains clindamycin palmitate hemihydrate equivalent to 0.6 g of clindamycin. Each 1.2-g multiple-dose vial contains clindamycin palmitate hemihydrate equivalent to 1.2 g of clindamycin. The product also contains benzyl alcohol and other preservatives.

**NATURAL HISTORY**

Clindamycin Injection, USP is not intended for long-term use. Clindamycin injection is most effective when used for short courses of treatment. The duration of treatment should be determined by the response of the patient and the microbiology of the causative organism. Clindamycin injection should be discontinued when control of infection is achieved.

**REFERENCES**


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Clindamycin Injection, USP

**Sensitivities:**

- Clindamycin has been associated with the following allergic reactions: Rash
- Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been reported
- Local reactions: Injection site reactions may occur

**Preservation:**

- Clindamycin phosphate must be diluted prior to IV administration. The concentration of clindamycin in solution for injection should not exceed 16 mg/mL.

**Stability:**

- Physical and chemical stability: The reconstituted solution is stable on standing at room temperature for at least 24 hours. Do not freeze. After reconstitution, the solution is stable for 12 hours if stored at 2-8°C.