CLINCENT GEL PRESCRIBING INFORMATION

Clindamycin Phosphate 1% Gel

COMPOSITION

Each g of **Clincent Gel** contains:	
Clindamycin phosphate USP equivalent to clindamycin in a gel vehicle	10 mg

CLINICAL PHARMACOLOGY

Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to clindamycin which has antibacterial activity. Clindamycin inhibits bacteria protein synthesis at the ribosomal level by binding to the 50S ribosomal subunit and affecting the process of peptide chain initiation. *In vitro* studies indicate that clindamycin inhibits *Propionibacterium acnes* cultures at a minimum inhibitory concentration (MIC) of 0.4 µg/mL.

Cross resistance has been demonstrated between clindamycin and lincomycin. Antagonism has been demonstrated between clindamycin and erythromycin.

Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0-3 ng/mL) and less than 0.2% of the dose is recovered in urine as clindamycin.

Clindamycin activity has been demonstrated in comedones from acne patients. Free fatty acids on the skin surface are decreased from approximately 14% to 2% following application of clindamycin.

INDICATIONS

Clincent Gel is indicated for topical application in the treatment of mild to moderate inflammatory acne vulgaris, either alone or in combination with other anti-acne products.

DOSAGE & ADMINISTRATION

Apply a thin film of **Clincent Gel** twice daily to the skin where acne lesions appear. Use enough to cover the entire affected area lightly.

CONTRAINDICATIONS

Clincent Gel is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

WARNINGS

Orally and parenterally administered clindamycin has been associated with severe colitis, which may end fatally. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin.

Studies indicate that a toxin(s) produced by Clostridia is one of the primary causes of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal

pseudomembranous colitis. Stool culture for Clostridium difficile and stool assay for C. difficile toxin may be helpful diagnostically.
When significant diarrhea occurs, the drug should be discontinued. Large bowel endoscopy should be considered to establish a definitive diagnosis in cases of severe diarrhea. Antiperistaltic agents, such as opiates and diphenoxylate with atropine, may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*.
Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with clindamycin.

PRECAUTIONS

General: Clincent Gel should be prescribed with caution in atopic individuals.

Pregnancy: Category B: Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin ranging from 100 to 600 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to clindamycin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, **Clincent Gel** should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether clindamycin is excreted in human milk following use of **Clincent Gel**. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children under the age of 12 have not been established.

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.

ADVERSE REACTIONS

Local effects: Burning, itching, dryness, erythema and peeling.
Systemic effects: Cases of diarrhea, bloody diarrhea and colitis [including pseudomembranous colitis] have been reported as adverse reactions in patients treated with oral and parenteral formulations of clindamycin and rarely with topical clindamycin. Abdominal pain and gastrointestinal disturbances as well as gram-negative folliculitis have also been reported in association with the use of topical formulations of clindamycin.

PRESENTATION

Clincent Gel is available in a tube of 20 g.

STORAGE

Store at a temperature not exceeding 25°C. Do not freeze.