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**Dalacin T™**  
Clindamycin phosphate



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Clindamycin phosphate

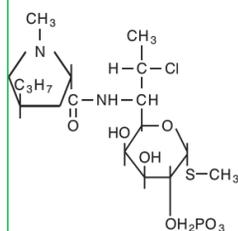


Pharmacia  
& Upjohn

FOR EXTERNAL USE

**Description**

Dalacin T Topical Solution contains clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per milliliter in an alcohol and water solution. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxy group of the parent antibiotic lincomycin. The solution also contains isopropyl alcohol, propylene glycol and water. The chemical structure of clindamycin phosphate is:



7(S)-chloro-7-deoxylincomycin-2-phosphate

**Clinical pharmacology**

**Microbiology**

Although clindamycin phosphate is inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin. Phosphatases on the skin hydrolyze clindamycin phosphate to clindamycin base. Clindamycin has been shown to have *in vitro* activity against isolates of *Propionibacterium acnes*. This may account for its usefulness in acne. In addition, clindamycin has shown a wide range of *in vitro* activities that are described in the inserts for oral and parenteral administration. Cross resistance has been demonstrated between clindamycin and lincomycin. Antagonism has been demonstrated between clindamycin and erythromycin. Clindamycin activity has been demonstrated in comedonal extracts from acne patients. The mean concentration of antibiotic activity in comedonal extracts was 1.4 mcg/ml. Clindamycin *in vitro* inhibits all *Propionibacterium acnes* cultures tested (MICs 0.4 mcg/ml). Free fatty acids on skin surface have been decreased from approximately 14% to 2% following application of topical clindamycin. Results of studies designed to detect clindamycin or clindamycin activity in blood or urine following topical application of clindamycin phosphate as provided in this preparation have been negative. However, studies of penetration into human skin with radiolabeled clindamycin hydrochloride have shown that approximately 10% of the dose is absorbed as indicated by concentration in the stratum corneum. Microbiological assay of the urine of clindamycin hydrochloride topically treated patients has shown varying concentrations of the antibiotic. No absorption of topically applied clindamycin phosphate has been observed, however it is theoretically possible that the clindamycin in this topical preparation could be absorbed.

**Indications**

Dalacin T Topical Solution (clindamycin phosphate) is indicated in the treatment of acne vulgaris. In a comparison with oral tetracycline, Dalacin T Topical Solution reduced acne lesions by 61% compared to 49% for tetracycline. In additional controlled studies, Dalacin T Topical Solution caused a 58% reduction in acne lesions compared to a 33% reduction with placebo (alcoholic vehicle).

**Contra-indications**

Dalacin T Topical Solution (clindamycin phosphate) is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

**Warnings**

Diarrhea, bloody diarrhea, non-specific colitis and pseudomembranous colitis (antibiotic associated colitis) have been reported with many antibiotics used systemically including clindamycin. No serious diarrhea or pseudomembranous colitis occurred in controlled clinical trials with the Dalacin T Topical Solution. However, it is theoretically possible that clindamycin could be present systemically through absorption from the skin surface. When it is applied topically, the physician should be alert to the remote possibility of an antibiotic induced severe diarrhea or colitis.

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If significant diarrhea should occur during therapy, the drug should be discontinued. Significant diarrhea (which theoretically may occur up to several weeks post therapy) should be managed as if antibiotic-associated. Studies indicate a toxin(s) produced by *Clostridia* (especially *Clostridium difficile*) is the principal direct cause 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. Anti-cholinergics and anti-peristaltic agents may worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *C. difficile*. The usual adult dosage is 500 mg vancomycin orally every 6 hours for a period of 7 to 10 days. Mild cases showing minimal mucosal changes may respond to simple drug discontinuance. Moderate to severe cases, including those showing ulceration or pseudomembrane formation, should be managed with fluid, electrolyte, and protein supplementation as indicated. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. Corticoid retention enemas and systemic corticoids may be of help in persistent cases. Other causes of colitis should be considered. A careful inquiry should be made concerning previous sensitivities to drugs and other allergens.

**Precautions**

Dalacin T Topical Solution (clindamycin phosphate) contains an alcohol base which will cause burning and irritation of the eye. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), bathe with copious amounts of cool tap water. The solution has an unpleasant taste and caution should be exercised when applying the medication around the mouth. Dalacin T Topical Solution should be prescribed with caution in atopic individuals. Concomitant use of other available acne preparations, e.g. benzoyl peroxide, retinoic acid, has been reported in uncontrolled studies. Safety for use of Dalacin T Topical Solution in pregnancy has not been established. It is not known whether clindamycin is excreted in human milk following use of Dalacin T Topical Solution. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

**Adverse reactions**

Reports of side effects with Dalacin T Topical Solution (clindamycin phosphate) have been infrequent. Irritation, stinging and erythema (believed to be caused by the alcoholic vehicle) were reported. Gastrointestinal reactions (diarrhea, nausea and vomiting) were reported by six patients who were treated with Dalacin T Topical Solution. None of these were considered drug related by the reporting physician (see also "Warnings" section). Single reports were made of sore throat, headache, dryness, urinary frequency and contact dermatitis. Two cases of fatigue and two cases of oily skin were reported. Dalacin T Topical Solution was applied twice daily for 56 days or longer to volunteers. The medication was well tolerated.

**Dosage and administration**

The medicine is available in bottles. The medicine that comes in a bottle has a separate applicator and cap. To use the applicator: 1) remove cap from bottle and discard, 2) firmly press applicator into bottle, 3) seal firmly by tightening domed-cap. The pharmacist may have assembled the bottle for you, in which case the applicator top will already be attached to the bottle. The applicator top may then be used to apply the medicine directly to the skin. The bottle should be tilted and pressed firmly against the skin using a dabbing rather than a rolling motion. Reducing the pressure will decrease the flow. Apply a thin film of Dalacin T Topical Solution (clindamycin phosphate) twice daily to affected area. How supplied Dalacin T Topical Solution (clindamycin phosphate) is available in 30 and 60 ml applicator bottles (10 mg clindamycin per milliliter). The applicator is designed so that the solution may be applied directly to the involved skin.

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|                  | Project No.                          | Artwork Number | Description                            |             | Country            |
|                  | 9914                                 | 12043200       | Dalacin T Solution                     |             | Middle East        |
| rev. 08JUN11     | Dimensions                           |                | Drawing No.                            | SKU No.     | Item               |
|                  | 15" x 4.1875" Folds to: 4.1875" x 1" |                | DWG-101457-00                          | 2233 & 2234 | Insert             |
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| Mgr              | M. Wolpert                           | Rev            | GA                                     | PR          | GS / ART REV (LCA) |
| GS               | N. DeShong                           | 1              |  |             | CHANGES            |
| GA               | L. Nelson                            |                |  |             | OK                 |