



DANALLI[®] T
Clindamycin

Description:

DANALLI[®] T is an Alcoholic topical solution of Clindamycin Phosphate. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic. Although Clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts this compound to the antibacterially active Clindamycin.

Properties:

Clindamycin is a lincosamide antibiotic with a primarily bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Cross resistance has been demonstrated between Clindamycin and Lincomycin. Antagonism has been demonstrated between Clindamycin and Erythromycin.

Following multiple topical applications a 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. Clindamycin in vitro inhibits all *Propionibacterium acnes* cultures tested. Free fatty acids on the skin surface have been decreased from approximately 14% to 2% following application of Clindamycin.

Indications:

DANALLI[®] T topical solution is indicated for the treatment of acne vulgaris.

Dosage and administration:

Apply a thin film of DANALLI[®] T topical solution twice daily to the affected area.

Patient notes:

- Wash affected areas, prior to application, with warm water and soap; rinse and pat dry.
- DANALLI[®] T topical solution 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 medication around the mouth.
- After washing or shaving, it is best to wait 30 minutes before applying. The Alcohol may irritate freshly washed or shaved skin.

- For DANALLI[®] T topical solution 30 ml, follow these instruction:

- * Remove cap and discard, press applicator into the bottle and seal firmly by tightening the cap.
- * Use the applicator with a dabbing motion instead of a rolling motion. You can make the medicine flow faster from the applicator tip by slightly increasing the pressure against the skin.

- For DANALLI[®] T topical solution 50 ml, follow these instruction: Squeeze few drops of the solution on a small piece of cotton and apply to affected area.

Contraindications:

Clindamycin topical solution is contra-indicated in patients previously found to be hypersensitive to this antibiotic. Although cross-sensitization to Lincomycin has not been demonstrated, it is recommended that Clindamycin topical solution is not used in patients who have demonstrated Lincomycin sensitivity.

Clindamycin topical solution is contraindicated in individuals with a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

Precautions:

- Products containing Benzoyl peroxide should not be used concurrently with Clindamycin Topical Solution.
- Oral and parenteral Clindamycin, as well as most other antibiotics, have been associated with severe pseudomembranous colitis. Post-marketing studies, however, have indicated a very low incidence of colitis with Clindamycin topical solution. The physician should, be alert to the development of antibiotic associated diarrhea or colitis. If significant or prolonged diarrhea occurs, the product should be discontinued immediately.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with Clindamycin.

Studies indicate a toxin(s) produced by *Clostridium difficile* is the major cause of antibiotic associated colitis. Colitis is usually



characterized by persistent, severe diarrhea and abdominal cramps. Endoscopic examination may reveal pseudomembranous colitis. Stool culture for *C. difficile* and/or assay for *C. difficile* toxin may be helpful to diagnosis.

Vancomycin is effective in the treatment of antibiotic-associated colitis produced by *C. difficile*. The usual dose is 125 - 500 mg orally every 6 hours for 7 - 10 days. Additional supportive medical care may be necessary.

Mild cases of colitis may respond to discontinuance of Clindamycin alone. Colestyramine and Colestipol resins have been shown to bind *C. difficile* toxin in vitro, and Colestyramine has been effective in the treatment of some mild cases of antibiotic-associated colitis. Colestyramine resins have been shown to bind Vancomycin; therefore, when both Colestyramine and Vancomycin are used concurrently, their administration should be separated by at least two hours.

- Topical Clindamycin should be prescribed with caution to atopic individuals.
- Use only water-base cosmetics and do not apply too heavily or too often.
- Safety and effectiveness in children under the age of 12 years have not been established.
- Avoid using near heat, open flame or while smoking because it is flammable.

Use during pregnancy and lactation:

Pregnancy category **B**

Pregnancy: Safety for use in pregnancy has not been established. 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, this drug should be used during pregnancy only if clearly needed.

Lactation: It is not known whether Clindamycin is excreted in human milk following use of 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.

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.

Side effects:

Side effects reported in clinical trials have been minor and of a similar incidence to placebo.

Skin dryness is the most common side effect seen with the topical solution. In addition, the following side effects have been reported with the use of topical Clindamycin:

Eye disorders: Stinging of the eye.

Gastrointestinal disorders: Abdominal pain, gastrointestinal disturbances.

Infections: Gram-negative folliculitis.

Skin and subcutaneous skin disorders: Skin irritation, contact dermatitis, skin oiliness, urticaria.

Overdosage:

Topically applied Clindamycin can be absorbed in sufficient amounts to produce systemic effects.

Storage conditions:

Store between 15 - 30°C. Keep container tightly closed.

Presentation:

DANALLI® T **Topical Solution:** Each 1 ml contains Clindamycin Phosphate equivalent to Clindamycin 10 mg in bottles of 30 and 50 ml.

Excipients:

Isopropyl Alcohol, Propylene Glycol & Purified Water.

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

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UNION OF ARAB PHARMACISTS**

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