



CLINDAMYCIN 1% TOPICAL SOLUTION

COMPOSITION:

Clindamycin Phosphate equivalent to Clindamycin 1% w/v

Methylparaben 0.08% w/v and Propylparaben 0.02% w/v as preservatives. Isopropyl Alcohol 44% v/v as disinfectant.

PRESENTATION:

Colourless solution.

INDICATIONS:

Treatment of acne vulgaris.

PHARMACOLOGY:*Mechanism of Action:*

Clindamycin phosphate is the ester of clindamycin [7-(S)-chlorolincomycin], a semi-synthetic antibiotic. Clindamycin has been shown to have in vitro activity against isolates of *Propionibacterium acnes*. This may account for its usefulness in acne. Clindamycin has no fungicidal activity.

Pharmacokinetics:

When applied topically, clindamycin has been shown to be absorbed from the skin in small amounts. Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin/mL in an isopropyl alcohol and water solution, very low levels of clindamycin are present in the serum (0-3 ng/mL) and <0.2% of the dose is recovered in urine as clindamycin.

DOSAGE & ADMINISTRATION:

Apply a thin film of the solution twice daily to affected area.

Directions for use:

1. Wash and dry the affected area.
2. Apply the medication sparingly to the affected area. Avoid contact with eyes and mucous membrane.
3. Use dabbing motion of the sponge of the applicator rather than rolling motion. If sponge dries out, invert the bottle and depress the sponge several times until it becomes moist.

CONTRAINDICATION:

Hypersensitivity to clindamycin or lincomycin, history of regional enteritis, ulcerative colitis or antibiotic-associated colitis. **Its use in newborns is contraindicated.**

PRECAUTIONS:

Clindamycin therapy has been associated with severe colitis which may end fatally. The physician should be alerted to the development of antibiotic-associated diarrhoea or colitis. If diarrhoea occurs, the product should be discontinued immediately. Patients with a history of the Crohn's disease and ulcerative colitis should be observed with caution. Prescribe with caution in atopic individuals. Prolonged use of this product for several months must be under the control of a physician.

It should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infection. Avoid contact with eyes.

Use in Pregnancy and Lactation:

Safe use of topical clindamycin in pregnancy has not been established. Caution should be exercised when clindamycin is given during breast feeding.

SIDE EFFECTS:

Topical applications may be associated with local irritation and contact dermatitis. Sufficient clindamycin may be absorbed to produce systemic effects that have been associated with colitis. Other side effects have been reported with the use of topical clindamycin including gastrointestinal effects, oily skin and gram-negative folliculitis.

DRUG INTERACTION:

None.

OVERDOSAGE AND TREATMENT:

This product is intended for topical use only. In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), rinse affected area with copious amounts of water. Topically applied clindamycin phosphate can be absorbed in sufficient amounts to produce systemic effects.

STORAGE:

Keep container well closed. Store below 30°C. Protect from light.

PACK QUANTITIES:

30ml frosted borosilicate glass bottle with sponge applicator. The applicator is designed so that the solution may be applied directly to the affected area.

Further information can be obtained from doctor, pharmacist or the manufacturer.

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Product Registration Holder and Manufacturer



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