

MEDACIN T[®]

(clindamycin phosphate USP)



PHARMACEUTICAL PRESENTATIONS:

MEDACIN T - TOPICAL SOLUTION
MEDACIN T - GEL
MEDACIN T - LOTION

COMPOSITION:

Each ml contains: clindamycin phosphate USP equivalent to clindamycin 10mg.

Each gram contains: clindamycin phosphate USP equivalent to clindamycin 10 mg.

PROPERTIES:

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. Phosphatases on the skin hydrolyze clindamycin phosphate to clindamycin base. Clindamycin has shown to have *in-vitro* activity against isolates of propionibacterium acnes. This may account for its usefulness in acne. Cross-resistance has been demonstrated between clindamycin and lincomycin. Antagonism has been also 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 1.4mcg/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.

INDICATION:

MEDACIN T (clindamycin phosphate) is indicated in the treatment of acne vulgaris.

CONTRA-INDICATIONS:

MEDACIN T (clindamycin phosphate) is contra-indicated 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:

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 pseudo-membranous colitis occurred in controlled clinical trials with the clindamycin phosphate. However, it is theoretically possible that clindamycin could be present systemically through its absorption from the skin surface.

SPECIAL WARNINGS:

Products containing benzoyl peroxide should not be used concomitantly with Medacin T.

PREGNANCY & LACTATION:

Safety has not been established

PRECAUTIONS:

MEDACIN T 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. MEDACIN T should be prescribed with caution in atopic individuals.

ADVERSE REACTIONS:

Reports of side effects with MEDACIN T (clindamycin phosphate) have been infrequent. Irritation, stinging and erythema (believed to be caused by the alcoholic vehicle) were reported.

Single reports were made of sore throat, headache, dryness, urinary frequency and contact dermatitis.

DIRECTION FOR USE & DOSAGE:

- Before use, clean & dry the skin area, to be treated.
- Shake lotion before use.
- Spread gel / lotion evenly on affected area.
- Topical Solution:
 - a) Apply a thin film of medication to the affected area. Use sparingly, avoiding eyes and mouth.
 - b) Use dabbing motion of the tip rather than a rolling action. If tip becomes dry, invert the bottle and depress tip several times until it becomes moist.
- In the event of accidental contact with sensitive surfaces (eye, abraded skin, mucous membranes), bathe with copious amounts of cool tap water.
- Use twice daily.

STORAGE: Store below 25°C for gel/lotion.

Store below 30°C for topical solution.

- ◆ Do not refrigerate.
- ◆ Do not use after the expiry date stated on the label.
- ◆ Do not use if there is any physical change on the product.
- ◆ Keep out of reach of children.

PACKAGING PRESENTATION:

MEDACIN T - Lotion: Bottle of 30 mL.

MEDACIN T - Gel: Aluminum collapsible tube of 30 gm.

MEDACIN T - Topical solution: 30 mL, applicator bottle designed for the direct application of the solution to the affected skin.

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 medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Mfd. by:

MEDPHARMA

PHARMA & CHEM. IND'S (L.L.C.)

Sharjah

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