Pfizer

ڈالانسین ٹی

Dalacin T®

(Clindamycin Phosphate)

Topical Lotion

DESCRIPTION

DALACIN T® topical lotion contains clindamycin phosphate equivalent to 10 mg clindamycin per gram. Clindamycin phosphate is a water soluble ester of the semi-synthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin.

THERAPEUTIC INDICATIONS

DALACIN T® topical lotion is indicated in the treatment of acne vulgaris.

POSOLOGY AND METHOD OF ADMINISTRATION

Route of administration:

Topical (external use only). Apply a thin film of DALACIN T® topical lotion twice daily to the affected area.

DALACIN T® topical lotion should be shaken before using.

CONTRAINDICATIONS

Topical clindamycin is contraindicated in individuals with a history of hypersensitivity to clindamycin or lincomycin. Clindamycin topical is contraindicated in individuals with a history of antibiotic-associated colitis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Oral and parenteral clindamycin, as well as most other antibiotics, have been associated with severe diarrhea and pseudomembranous colitis. Use of the topical formulation of clindamycin results in absorption of the antibiotic from the skin surface. Diarrhea and colitis have been reported infrequently with topical clindamycin. Therefore, the physician should be alert to the possible development of antibiotic-associated diarrhea or colitis. If significant or prolonged diarrhea occurs, the drug should be discontinued and appropriate diagnostic procedures and treatment provided as necessary.

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

Topical clindamycin solution contains an alcohol base and can cause burning and irritation of eyes, mucous membranes and abraded skin.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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.

PREGNANCY AND LACTATION

Use in Pregnancy:

Oral and subcutaneous reproductive toxicity studies in rats and rabbits 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.

Use in Nursing Mothers:

It is not known whether clindamycin is excreted in human milk following use of topical clindamycin. 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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effect of clindamycin on the ability to drive or operate machinery has not been systematically evaluated.

UNDESIRABLE EFFECTS

The following adverse effects have been reported with the use of clindamycin phosphate topical lotion.

Eye disorders:
stinging of the eye

Gastrointestinal disorders:
abdominal pain, gastrointestinal disturbances

Infections and infestations:
gram-negative folliculitis

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

OVERDOSE

Topically applied clindamycin can be absorbed in sufficient amounts to produce systemic effects. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Microbiology:

Although clindamycin phosphate is

inactive *in vitro*, rapid *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin.

Clindamycin has been shown to have *in vitro* activity against isolates of the following organisms:

Aerobic gram positive cocci, including:
- Staphylococcus aureus (penicillinase and non-penicillinase producing strains). When tested by *in vitro* methods, some staphylococcal strains originally resistant to erythromycin rapidly develop resistance to clindamycin.
- Staphylococcus epidermidis (penicillinase and non-penicillinase producing strains). When tested by *in vitro* methods, some staphylococcal strains originally resistant to erythromycin rapidly develop resistance to clindamycin.
- Streptococci (except *Enterococcus faecalis*)
- Pneumococci

Anaerobic gram negative bacilli, including:
- *Bacteroides* species (including *Bacteroides fragilis* group and *Bacteroides melaninogenicus* group)
- *Fusobacterium* species

Anaerobic gram positive nonsporeforming bacilli, including:
- *Propionibacterium*
- *Eubacterium*
- *Actinomyces* species

Anaerobic and *microaerophilic gram positive cocci*, including:
- *Peptococcus* species
- *Peptostreptococcus* species
- Microaerophilic streptococci

Clostridia:
Clostridia are more resistant than most anaerobes to clindamycin. Most *Clostridium perfringens* are susceptible, but other species, e.g., *Clostridium sporogenes* and *Clostridium tertium* are frequently resistant to clindamycin. Susceptibility testing should be done.

Cross resistance has been demonstrated between clindamycin and lincomycin.

Antagonism has been demonstrated between clindamycin and erythromycin *in vitro*. The clinical significance of this interaction is unknown.

Pharmacokinetic Properties
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. The mean concentration of antibiotic activity in extracted comedones after application of clindamycin topical solution for 4 weeks was 597 mcg/g of comedonal material (range 0–1490). Clindamycin *in vitro* inhibits all *Propionibacterium acnes* cultures tested (MICs 0.4 mcg/mL). Free fatty acids on the skin surface have been decreased from approximately 14% to 2% following application of clindamycin.

Geriatric Use
Clinical studies for topical clindamycin did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

SHELF LIFE
24 months

NATURE AND CONTENTS OF CONTAINER
DALACIN T® topical lotion contains clindamycin phosphate equivalent to 10 mg clindamycin per gram, is available in dispensing bottle containing 30 mL of lotion.

DIRECTION FOR USE
Shake the bottle before use and apply thinly twice daily to the effected area.

For external use only.

WARNING
Avoid contact with eyes.
Keep cap tightly closed after use.

INSTRUCTIONS
Avoid exposure to heat & sunlight.
Store below 30°C.
Keep out of the reach of children.

CAUTION
To be sold on the prescription of a registered medical practitioner only.

طریقہ استعمال:
استعمال سے پہلے بوتل کو ہلالیں اور
متاثرہ حصے پر دن میں دو مرتبہ لگائیں۔

صرف بیرونی استعمال کے لئے۔

احتیاط:
آنکھوں پر لگنے سے بچائیں۔
استعمال کے بعد ڈھکن کو پورے طور پر بند کردیں۔

ہدایات: دوا کو گرمی اور سورج کی روشنی سے بچائیں۔
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔

تاکید: صرف رجسٹرڈ میڈیکل پریکٹشنر کے نسخہ پر فروخت کریں۔

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