Avalon Pharma

AVOCIN 1% TOPICAL SOLUTION

Clindamycin Phosphate Equivalent to 1% Clindamycin

Description:
Avocin 1% Topical Solution contains Clindamycin Phosphate at concentration equivalent to 10mg Clindamycin per 1ml in 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 Purified Water.

Composition:
Clindamycin Phosphate equivalent to Clindamycin 10 mg per 1ml solution (1%).

Indications:
Avocin 1% Topical Solution is indicated in the treatment of acne vulgaris.

Contraindications:
Avocin 1% Topical Solution is contraindicated in individuals with:
- History of hypersensitivity to preparations containing Clindamycin or Lincomycin.
- History of regional enteritis or ulcerative colitis.
- History of antibiotic-associated colitis.

Pharmacology:
Clindamycin Phosphate is inactive and should be converted to the active Clindamycin. This happens by phosphatases on the skin which hydrolyzes Clindamycin Phosphate to Clindamycin.
Active clindamycin has been shown to have *in vitro* activity against isolates of *Propionibacterium acnes*. This may account for and explain its usefulness in treatment of acne.
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 (MIC 0.4mcg/ml). Free fatty acids on skin surface have been decreased from approximately 14% to 2% following application of topical Clindamycin.

Pharmacokinetics:
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 has 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.

Precautions:
- For topical use only.
- Avocin 1% Topical Solution contains an Isopropyl Alcohol base, so avoid the contact with eyes as it will cause burning and irritation. In case of accidental contact with eyes, abraded skin or mucous membranes, wash with copious amount of cold tap water.
- The solution has unpleasant taste and caution should be considered when applying around the mouth.
- Avocin 1% Topical Solution should be prescribed with caution in atopic individuals.

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 Clindamycin phosphate 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. 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 the 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.

Direction of use:
Apply a thin film of Avocin 1% Topical Solution twice daily to the affected area.

Pregnancy and Lactation:
Safety for use of Clindamycin Phosphate topical solution in pregnancy has not been established. It is not known whether Clindamycin is excreted in human milk following use of Avocin 1% 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.

Side effects:
The most commonly reported medical events were: skin dryness, irritation, stinging and erythema. (believed to be caused by the Alcohol vehicle). Also diarrhea and gastrointestinal reactions were reported.
Rarely reported adverse effects include: headache, urinary frequency, contact dermatitis and oily skin.

Storage:
Store at room temperature (15°- 30°C).

Presentation:
Avocin 1% Topical Solution is available in 30 ml plastic bottle with applicator.

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 your self interrupt the period of treatment prescribed for you.