DATA SHEET

TOPICIL
Clindamycin 1% topical solution as clindamycin phosphate Ph. Eur.

Presentation
A clear alcoholic solution in a 28 ml clear glass bottle with dab-o-matic top.

Uses

Actions
Clindamycin phosphate is inactive in-vitro, however, rapid in-vivo hydrolysis releases the lincosamide antibiotic clindamycin. Clindamycin has in-vivo activity against all isolates of propionibacterium acnes (MICs 0.4 µg/ml) and activity has been demonstrated in comedones from acne patients. The mean concentration of antibiotic activity in extracted comedones after application of the solution for four weeks was 597 µg/g of comedonal material (range 0-1490). It appears that topical administration of clindamycin can also reduce free fatty acid levels on the skin with free fatty acids on the skin surface decreasing from approximately 14 % to 2 % following application of clindamycin.

Pharmacokinetics
Clindamycin is absorbed through the skin after multiple applications with serum concentrations being in the range 0-3 ng/mL. This represents only 0.2 % of the peak concentration achieved after oral administration of a 150 mg capsule. It has also been shown that there is no accumulation after multiple oral doses. Absorbed clindamycin is widely distributed, however, it does not appear in the CSF even in the presence of inflamed meninges. The biological half-life is approximately 2.5 hours although this may be increased in the presence of severely reduced renal function. Clindamycin is eliminated by metabolism to inactive metabolites.

Less than 0.25 % of a dose is recovered in the urine as clindamycin.

Indications
Treatment of acne unresponsive to non-antibiotic therapy.
Dosage and Administration

Apply a thin film twice daily to the affected area.

Contraindications

History of hypersensitivity to preparations containing clindamycin or lincomycin. History of regional enteritis, ulcerative colitis or antibiotic-associated colitis.

Warnings and Precautions

The alcohol base of TOPICIL solution will cause burning and irritation of the eye or mucous membranes if accidental contact occurs. If such an event occurs apply copious amounts of water. Similarly, the solution has an unpleasant taste and caution is required if application around the mouth is required.

Since clindamycin is absorbed after topical administration, administration may rarely give rise to diarrhoea, bloody diarrhoea and colitis including pseudomembranous colitis. Symptoms may develop after a few days, weeks or months after initiation of therapy. Symptoms have also been observed to begin several weeks after cessation of therapy.

A primary cause is a toxin(s) produced by clostridium difficile. The colitis is characterised by severe persistent diarrhoea, severe abdominal cramps and may be associated with the passage of blood and mucus.

If significant diarrhoea occurs while using TOPICIL, the topical use of clindamycin should be stopped and large bowel endoscopy considered for severe diarrhoea.

An effective treatment of antibiotic-associated pseudomembranous colitis is oral vancomycin 500mg-2g daily in 4 divided doses for 7-10 days. Mild cases may respond to clindamycin discontinuation while moderate to severe cases may require fluid, electrolyte and protein supplementation. Cholestyramine and colestipol resins can bind the toxin, however, antiperistaltic agents such as opiates or diphenoxylate may prolong or worsen the condition.

Reproduction studies performed in rats and mice using subcutaneous and oral doses ranging from 100-600mg/kg/day clindamycin have revealed no evidence of impaired fertility or harm to the foetus.

Use in Pregnancy: Category A. (Prescribing Medicine in Pregnancy 4th Ed.)
Clindamycin has been used by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Use in Lactation: It is known that clindamycin administered by either the oral or parenteral route is excreted into breast milk. Consequently this may also happen after topical administration. Nursing should not be undertaken while the patient is using clindamycin.
**TOPICIL** should be prescribed with caution in **atopic** individuals.

**Paediatric Use:** Safety and effectiveness in children under the age of 12 has not been established.

Clindamycin topical solution is presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

**Adverse Effects**

Adverse effects have been reported rarely with clindamycin topical solutions. Those reported include: dry skin, oily skin, skin irritation, contact dermatitis, eye stinging, gram negative folliculitis and GI disturbances or abdominal pain occasionally associated with diarrhoea, bloody diarrhoea and colitis (including pseudomembranous colitis).

Since clindamycin may be absorbed after topical administration, the following effects should also be noted since they have occurred after oral or parenteral administration: hypersensitivity reactions such as maculopapular rash and urticaria or erythema multiforme resembling Stevens-Johnson syndrome; jaundice and liver function test abnormalities; renal dysfunction in the form of azotemia, oliguria and/or proteinuria; transient neutropenia and eosinophilia; and polyarthritis.

**Interactions**

Products containing benzoyl peroxide should not be used concurrently with **TOPICIL**.

**Overdosage**

No cases have been reported.

**Pharmaceutical Precautions**

Store below 25 °C. Flammable. Keep away from heat and flame. The shelf-life of Topicil solution is 36 months.

**Medicine Classification**

Prescription Only Medicine

**Package Quantities**

28 ml
Further Information

Clindamycin phosphate is L-threo-a-D-galacto-octopyranoside,methyl-7-chloro-6,7,8-trideoxy-6-[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-,2-(dihydrogen phosphate),(2S-trans)-. Its molecular formula and weight are $C_{18}H_{34}ClN_2O_8PS$ and 504.96 respectively.

The structural formula of clindamycin hydrochloride is:

![Structural formula of clindamycin hydrochloride](image)

Other ingredients are: Purified water, Isopropyl alcohol and Propylene glycol.

Name and Address

Douglas Pharmaceuticals Ltd.,
P.O. Box 45-027,
Auckland 8.

Ph: (09) 835-0660
Fax: (09) 835-0665

Date of Preparation

06 May 2009