New Zealand Data Sheet

1. PRODUCT NAME

Topicil® topical solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Topicil topical solution contains clindamycin phosphate 1% w/v, equivalent to 1% w/v clindamycin.

Excipient(s) with known effect

Contains propylene glycol. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A colourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Treatment of acne unresponsive to non-antibiotic therapy.

4.2. Dose and method of administration

Apply a thin film twice daily to the affected area.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

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 mucous.

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 500 mg-2 g 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.

Topicil should be prescribed with caution in atopic individuals.

Paediatric population

Safety and effectiveness in children under the age of 12 has not been established.

4.5. Interaction with other medicines and other forms of interaction

Products containing benzoyl peroxide should not be used concurrently with Topicil.

4.6. Fertility, pregnancy and lactation

Pregnancy

Category A. 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 foetus having been observed.

Breast-feeding

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.

Fertility

Refer to section 5.3.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable 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 azotaemia, oliguria and/or proteinuria; transient neutropenia and eosinophilia; and polyarthritis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://nzphvc.otago.ac.nz/reporting/

4.9. Overdose

No cases have been reported

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti-infectives for treatment of acne, ATC code: DA10AF01.

Action

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.

5.2. Pharmacokinetic properties

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.

5.3. Preclinical safety data

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

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Topicil topical solution contains propylene glycol, isopropyl alcohol, and purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Store at or below 25°C.

6.5. Nature and contents of container

Bottle, glass, 28 ml or 30 ml.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription medicine

8. SPONSOR

Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651
New Zealand
Phone: (09) 835 0660

9. DATE OF FIRST APPROVAL

18 October 1990

10. DATE OF REVISION OF THE TEXT

07 February 2019

Summary table of changes

Section Changed	Summary of new information
All	SPC format