

**SCHEDULING STATUS:** S4

**PROPRIETARY NAME AND DOSAGE FORM:**

DALACIN® T SOLUTION

DALACIN® T LOTION

**COMPOSITION:**

DALACIN T SOLUTION contains the following per ml:

Clindamycin phosphate equivalent to clindamycin base 10 mg

Excipients:

Isopropyl alcohol and propylene glycol

DALACIN T LOTION contains the following per ml:

Clindamycin phosphate equivalent to clindamycin base 10 mg

Methylparaben (preservative) 0,3 % m/m

Excipients:

Cetostearyl alcohol, glycerin, isostearyl alcohol, lexemul T, sodium lauroyl sarcosinate and stearic acid

**CATEGORY AND CLASS:**

A 20.1.6 Topical antibiotics

**PHARMACOLOGICAL ACTION:**

**Pharmacodynamic properties:**

Clindamycin inhibits bacterial protein synthesis at the level of the bacterial ribosome. The antibiotic binds preferentially to the 50S ribosomal subunit and affects the process of peptide chain initiation.

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

*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 between clindamycin and lincomycin has been demonstrated.

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

Free fatty acids on skin surface have been decreased from approximately 14 % to 2 % following application of topical clindamycin.

**Pharmacokinetic properties:**

Clindamycin activity has been demonstrated in comedonal extracts from acne patients. The mean concentration of antibiotic activity in comedonal extracts after 4 weeks of treatment was 597 µg/g of comedonal material (range 0 - 1 490).

Following multiple topical applications of clindamycin phosphate at a concentration equivalent to 10 mg clindamycin per ml in an isopropyl alcohol and water solution, low levels of clindamycin are present in the serum ( $\pm$  3 ng/ml) and less than 0,2 % of the dose is recovered in urine as clindamycin.

**INDICATIONS:**

DALACIN T SOLUTION and DALACIN T LOTION are indicated in the treatment of acne vulgaris associated with propionibacterium acnes activity.

**CONTRAINDICATIONS:**

DALACIN T SOLUTION and DALACIN T LOTION are contraindicated:

- In patients with a history of hypersensitivity to preparations containing clindamycin, lincomycin or to any components of these products.

- In patients with a history of antibiotic-associated colitis, ulcerative colitis or regional colitis (Crohn's disease).

**WARNINGS AND SPECIAL PRECAUTIONS:**

Topical, oral and parenteral clindamycin have been associated with severe diarrhoea and pseudomembranous colitis. If significant or prolonged diarrhoea occurs, the medication should be discontinued and appropriate diagnostic procedures and treatment provided as necessary. Use of DALACIN T results in absorption of the antibiotic from the skin surface (see Pharmacokinetic properties).

Diarrhoea, colitis and pseudomembranous colitis can develop at any time during treatment and up to several weeks following cessation of oral and parental therapy with DALACIN T.

Antiperistaltic medicines such as opiates and diphenoxylate may prolong and/or aggravate the colitis.

DALACIN T SOLUTION contains an alcohol base which can cause burning and irritation of the eyes, mucous membranes and abraded skin. 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.

DALACIN T SOLUTION should be prescribed with caution in atopic individuals.

**Effects on ability to drive and use machines:**

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

**INTERACTIONS:**

Systemic clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of neuromuscular blocking medicines. Therefore, neuromuscular blocking medicines should be used with caution in patients on treatment with DALACIN T.

### **HUMAN REPRODUCTION:**

Safety in pregnancy and lactation has not been established.

#### **Pregnancy:**

DALACIN T SOLUTION and DALACIN T LOTION should not be used in pregnancy.

#### **Lactation:**

Orally and parenterally administered clindamycin has been reported to appear in breast milk. The possibility of clindamycin in breastmilk after topical application cannot be excluded. Mothers on treatment with DALACIN T SOLUTION and DALACIN T LOTION should not breastfeed their infants.

### **DOSAGE AND DIRECTIONS FOR USE:**

Apply a thin film of DALACIN T SOLUTION or DALACIN T LOTION twice daily to the affected area.

DALACIN T LOTION should be shaken immediately before using.

### **SIDE EFFECTS:**

Side effects are categorised as follows:

Very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1\ 000$ ,  $< 1/100$ ); rare ( $\geq 1/10\ 000$ ,  $< 1/1\ 000$ ); very rare ( $< 1/10\ 000$ ), including isolated reports

<b>System organ class</b>	<b>Frequency</b>	<b>Side effect</b>
<i>Gastrointestinal disorders</i>	Common	Gastrointestinal disorders
<i>Skin and subcutaneous tissue disorders</i>	Very common	Skin irritation (burning, itching, erythema), dry skin, urticaria, peeling
	Common	Seborrhoea

**Post-marketing experience:**

Adverse reactions identified from post-marketing experience include the following:

<b>System organ class</b>	<b>Side effect</b>
<i>Infections and infestations</i>	Folliculitis
<i>Eye disorders</i>	Eye pain
<i>Gastrointestinal disorders</i>	Pseudomembranous colitis, abdominal pain
<i>Skin and subcutaneous tissue disorders</i>	Contact dermatitis

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

DALACIN T can be absorbed in sufficient amounts to produce systemic effects.

In the event of overdosage, treatment should be symptomatic and supportive.

**IDENTIFICATION:**

DALACIN T SOLUTION: Clear solution.

DALACIN T LOTION: A smooth white to off-white emulsion with no evidence of phase separation.

**PRESENTATION:**

DALACIN T SOLUTION is available in 30 ml applicator bottles (10 mg clindamycin per millilitre). The applicator is designed so that the solution may be applied directly to the involved skin.

DALACIN T LOTION is available in 30 ml plastic bottles (10 mg clindamycin per millilitre).

**STORAGE INSTRUCTIONS:**

DALACIN T Solution: Store at or below 25 °C.

DALACIN T Lotion: Store at or below 25 °C.

Keep out of reach of children.

**REGISTRATION NUMBER:**

DALACIN T SOLUTION: P/20.1.6/63

DALACIN T LOTION: Y/20.1.6/326

**NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:**

Date of registration:

DALACIN T SOLUTION: 14 April 1983

DALACIN T LOTION: 03 February 1992

Date of last SAHPRA approval: 05 April 2019

**BOTSWANA: S2**

**DALACIN T SOLUTION: B9311975**

**DALACIN T LOTION: B9311985**

**MALAWI: POM**

**DALACIN T SOLUTION: PMPB/PL135/25**

**NAMIBIA: S2**

**DALACIN T SOLUTION: 90/20.1.6/001304**

**DALACIN T LOTION: 04/20.1.6/0723**

**ZIMBABWE: PP**

**DALACIN T SOLUTION: 84/14.1.1/1823**