PRODUCT MONOGRAPH

Pr **DALACIN* T**

clindamycin phosphate topical solution USP

clindamycin 1% w/v

Antibiotic

Pfizer Canada Inc
17,300 Trans-Canada Highway
Kirkland, Quebec  H9J 2M5

Date of Revision: 09 February 2015

Submission Control No: 179533

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SUMMARY PRODUCT INFORMATION

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<th>Route of Administration</th>
<th>Dosage Form / Strength</th>
<th>Clinically Relevant Nonmedicinal Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topical</td>
<td>1% (10 mg/mL) of clindamycin (as clindamycin phosphate)</td>
<td>Propylene glycol (50 mg) (5.0% w/v), isopropyl alcohol (500 mg) (50.0% w/v)</td>
</tr>
</tbody>
</table>

For a complete listing see Dosage Forms, Composition and Packaging section.

INDICATIONS AND CLINICAL USE

DALACIN T (clindamycin phosphate) is indicated for the treatment of acne vulgaris.

Geriatrics (> 65 years of age):
Clinical studies of clindamycin did not include sufficient numbers of patients age 65 and over to determine whether they respond differently from younger patients.

Pediatrics
Safety and effectiveness in pediatric patients under the age of 12 have not been established.

CONTRAINDICATIONS

DALACIN T (clindamycin phosphate) is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin or to any ingredient in the formulation or component of the container (see DOSAGE FORMS, COMPOSITION AND PACKAGING).

DALACIN T is also contraindicated in individuals with a history of inflammatory bowel disease (including regional enteritis and ulcerative colitis), or a history of antibiotic-associated colitis (including pseudomembranous colitis).
WARNINGS AND PRECAUTIONS

General
FOR EXTERNAL USE ONLY. NOT FOR ORAL OR OPHTHALMIC USE.

DALACIN T (clindamycin phosphate) contains an alcohol base, isopropyl alcohol, which will cause burning and irritation of the eye. Avoid contact with eyes, mouth, lips, other mucous membranes, or areas of broken skin. In the event of accidental contact with sensitive surfaces bathe with copious amounts of cool tap water (see OVERDOSAGE).

The solution has an unpleasant taste and caution should be exercised when applying medication around the mouth.

Concomitant use of topical preparations containing alcohol should be avoided because they potentiate the drying action on the skin. The solvent vehicles in some of peeling, desquamating or abrasive agents as cleansers, medicated soaps or cosmetics are alcoholic and should be used with caution since a possible cumulative irritancy effect may occur in patients undergoing treatment.

DALACIN T should be prescribed with caution in atopic individuals.

Care should be exercised when treating patients with multiple medications. Resistance to clindamycin is often associated with resistance to erythromycin. It is therefore advisable to avoid concurrent use of the two agents either by topical or oral treatment (see DRUG INTERACTIONS).

Flammability
DALACIN T solution is flammable. Patients should avoid smoking or being near an open flame during application and immediately after use.

Gastrointestinal

Clostridium difficile-associated disease:

Clostridium difficile-associated disease (CDAD) has been reported with use of many antibacterial agents, including DALACIN T (clindamycin phosphate topical solution USP 1%). CDAD may range in severity from mild diarrhea to fatal colitis. It is important to consider this diagnosis in patients who present with diarrhea, or symptoms of colitis, pseudomembranous colitis, toxic megacolon, or perforation of colon subsequent to the administration of any antibacterial agent. CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

Treatment with antibacterial agents may alter the normal flora of the colon and may permit overgrowth of Clostridium difficile. C. difficile produces toxins A and B, which contribute to the development of CDAD. CDAD may cause significant morbidity and mortality. CDAD can be refractory to antimicrobial therapy.
If the diagnosis of CDAD is suspected or confirmed, appropriate therapeutic measures should be initiated. Mild cases of CDAD usually respond to discontinuation of antibacterial agents not directed against *Clostridium difficile*. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial agent clinically effective against *Clostridium difficile*. Surgical evaluation should be instituted as clinically indicated, as surgical intervention may be required in certain severe cases (see **ADVERSE REACTIONS**).

**Special Populations**

**Pregnant Women**: There are no adequate and well-controlled studies in pregnant women. Safety for use in pregnancy has not been established.

DALACIN T should not be used during pregnancy unless clearly needed and unless the expected benefits to the mother outweigh any potential risks to the fetus.

Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin ranging from 20 to 600 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to clindamycin except at doses that caused maternal toxicity. In one mouse strain, cleft palates were observed in treated fetuses; this response was not produced in other mouse strains or in other species, and therefore may be a strain specific effect. Oral and subcutaneous reproductive toxicity studies in rats and rabbits revealed no evidence of impaired fertility or harm to the fetus due to clindamycin, except at doses that caused maternal toxicity. Animal reproduction studies are not always predictive of human response.

**Nursing Women**: It is not known whether clindamycin is excreted in human milk following the use of topically-applied DALACIN T. However, orally and parenterally-administered clindamycin have been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, nursing should not be undertaken while a patient is using DALACIN T.

**ADVERSE REACTIONS**

**Adverse Drug Reaction Overview**

In a large U.S. postmarketing surveillance study among 1298 patients treated only with topical clindamycin phosphate solution, skin dryness/irritation, diarrhea or gastrointestinal symptoms were the most commonly reported medical events. Of those, 258 (19.9%) reported one or more of the following dermatological events. Among patients treated with oral antibiotics only, or no antibiotics, the percentage of patients reporting dermatologic event(s) was 20.8% and 25.4% respectively.
Dry skin    Irritation
Acne worse    Itching
Rash/redness    New Acne
Peeling    Sunburn
Discolouration    Contact Dermatitis
Urticaria

The following new gastrointestinal problems were reported in this surveillance study by 18.7% of the DALACIN T treated patients, 22.9% of the oral antibiotic treated patients, and 18.4% of the patients with no antibiotic exposure.

Abdominal Pain/cramps  "Nervous" stomach
Nausea    Ulcers
Flu/Virus    Vomiting
Indigestion    Colon problems
Gas/Bloating    (not colitis)

Cases of diarrhea, bloody diarrhea and colitis (including pseudomembranous colitis) have been reported as adverse reactions in patients treated with topical formulations of clindamycin. Diarrhea was reported by 55 of the 1298 (5%) DALACIN T patients, compared to 3.9% of control patients (See WARNINGS and PRECAUTIONS, Gastrointestinal, CDAD). In addition to the above, the following side effects have also been occasionally reported during drug treatment with DALACIN T: oily skin, eye pain and gram-negative folliculitis.

DRUG INTERACTIONS

Overview
Clinically important interactions between topical clindamycin and systemically coadministered drugs are unlikely, based on the low systemic exposure following multiple topical applications of clindamycin phosphate.

Clindamycin has been shown to have neuromuscular blocking properties and potential antagonism with erythromycin and aminoglycosides (see Table 1).

Drug-Drug Interactions
The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction.
Table 1 - Established or Potential Drug-Drug Interactions

<table>
<thead>
<tr>
<th>Proper name</th>
<th>Ref</th>
<th>Effect</th>
<th>Clinical comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuromuscular blocking agents</td>
<td></td>
<td>Clindamycin (parenterally-administered) has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents</td>
<td>Use with caution in patients receiving these agents concurrently.</td>
</tr>
<tr>
<td>Examples include: atracurium, doxacurium, pancuronium, vecuronium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS Clindamycin (parenterally-administered)</td>
<td>T</td>
<td>Clindamycin is reported to antagonize bactericidal activity of aminoglycosides in vitro. In vivo antagonism has not been demonstrated.</td>
<td>Use with caution in patients receiving such agents.</td>
</tr>
<tr>
<td>aminoglycosides</td>
<td>T</td>
<td>Antagonism has been demonstrated between clindamycin and erythromycin in vitro. Clindamycin and erythromycin may compete for the same protein binding site in bacteria.</td>
<td>Due to possible clinical significance the two drugs should not be administered concurrently.</td>
</tr>
<tr>
<td>erythromycin</td>
<td>T</td>
<td>Antagonism has been demonstrated between clindamycin and erythromycin in vitro. Clindamycin and erythromycin may compete for the same protein binding site in bacteria.</td>
<td>Due to possible clinical significance the two drugs should not be administered concurrently.</td>
</tr>
</tbody>
</table>

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

Drug-Food Interactions
Interactions with food have not been established.

Drug-Herb Interactions
Interactions with herbal products have not been established.

Drug-Laboratory Interactions
Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations
The safety and efficacy of DALACIN T lotion has not been demonstrated beyond 12 week’s duration.

Recommended Dose and Dosage Adjustment
Apply thin film of DALACIN T to the skin twice daily. Patients responding to DALACIN T should show improvement in 8 weeks. Treatment beyond 12 weeks may call for evaluation by
the physician.

**Administration**
DALACIN T is for external use only. Not for oral, intravaginal or ophthalmic use. Apply a thin film of DALACIN T twice daily to clean, dry skin of the whole area affected by acne not just to the pimples. Hands should be washed after application.

DALACIN T solution is flammable. Do not use the solution near flames or while you are smoking.

Unless skin is oily, washing 2 or 3 times a day with non-medicinal cleanser is enough. The face should not be washed for at least two hours after applying this medicine. After shaving, it is best to wait 30 minutes before applying the medicine because the alcohol in it may irritate freshly shaven skin.

To assist the patient, the pharmacist may assemble the bottle upon dispensing as follows:
1) remove cap from bottle and discard,
2) firmly press applicator into bottle,
3) seal firmly by tightening domed-cap.

**Missed Dose**
If a dose is missed, it should be applied as soon as remembered unless it is almost time for the next dose. The dose should not be doubled to make up for a missed dose.

**OVERDOSAGE**

For management of a suspected drug overdose, contact your regional Poison Control Centre.

**Symptoms**
DALACIN T contains isopropyl alcohol. Systemic absorption of isopropyl alcohol should be considered a possibility in the event of accidental ingestion.

Topically applied clindamycin phosphate can be absorbed in sufficient amounts to produce systemic side effects including abdominal pain, nausea, vomiting and diarrhea (see WARNINGS AND PRECAUTIONS).

The average biological half-life of clindamycin is 2.4 hours in the serum.

**Treatment**
No specific antidote is available. In the event of accidental ingestion, activated charcoal may be administered to aid in the removal of unabsorbed drug. General supportive measures are recommended.
In the event of accidental contact with sensitive surface (eye, abraded skin, mucous membrane) or excessive application of DALACIN T, the application site should be bathed with copious amounts of cool tap water (see WARNINGS AND PRECAUTIONS).

ACTION AND CLINICAL PHARMACOLOGY

**Mechanism of Action**
Clindamycin phosphate is inactive *in vitro* but *in vivo* hydrolysis converts this compound to the antibacterially active clindamycin. Clindamycin has been shown to have *in vitro* activity against isolates of *Propionibacterium acnes* which may account for its usefulness in acne. Clindamycin activity has been demonstrated in serum, urine and in comedonal extracts from acne patients.

The mean concentration of antibiotic activity in extracted comedones after application of DALACIN T (clindamycin phosphate) for 4 weeks was 597 μg/gram of comedonal material (range 60-1490). Clindamycin *in vitro* inhibits *Propionibacterium acnes* cultures tested.

STORAGE AND STABILITY

**Temperature:**
DALACIN T (clindamycin phosphate topical solution) should be stored at controlled room temperature (15° - 30°C).

**Light:**
Protect from exposure to heat and light.

**Other:**
- Keep in a safe place out of the reach and sight of children.
- Dalacin T is flammable. Keep away from flames.
- Do not freeze.
- Store the bottle upright.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL of DALACIN T (clindamycin phosphate topical solution) contains clindamycin phosphate equivalent to 10 mg clindamycin. The solution also contains isopropyl alcohol 50% v/v, propylene glycol and purified water. When needed, the pH of the solution is adjusted with hydrochloric acid and/or sodium hydroxide. DALACIN T is available in 30 and 60 mL bottles. A dab-o-matic applicator and cap is provided external to each bottle for placement into the bottle.
PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: clindamycin phosphate

Chemical name:

1. Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-trans(1-methyl-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo-a-D-galacto-,2-(dihydrogen phosphate), hydrate;

2. Lincomycin, 7(S)-chloro-7-deoxy-,2-phosphate, hydrate;

3. Clindamycin 2-phosphate hydrate

Molecular formula: \( \text{C}_{18}\text{H}_{34}\text{ClN}_{2}\text{O}_{8}\text{PS} \)

Molecular mass: 505

Structural formula:

Physicochemical properties: Clindamycin phosphate is a water soluble ester of clindamycin and phosphoric acid. The intact ester is essentially inactive as an antibacterial agent. Chemical or enzymatic hydrolysis of clindamycin phosphate is necessary to obtain the antibiotic activity of the clindamycin base. Clindamycin phosphate is a white to off-white, hygroscopic, crystalline powder which melts at about 175°C with decomposition. It has two acidic protons with pK1 = 0.964 and pK2 = 6.081. The partition co-efficient is 0.03. The pH of a solution of 10 mg/mL in water is between 3.5 and 4.5.
DETAILED PHARMACOLOGY

*In vitro* studies using human skin from leg amputations indicated that approximately 5 to 10% of a single application of 1% $^{3}$H-clindamycin solution penetrated the epidermis. Twice daily applications increased the total amount of clindamycin penetrating the skin but three times a day applications did not.

Clindamycin plasma concentrations were detectable ($\geq 0.5$ ng/ml) in 5 of 6 patients when 1% clindamycin phosphate was applied to approximately 300 cm$^2$ of the face every 12 hours for 6 doses. Peak concentrations in plasma ranged from 0 to 3.0 ng/ml which represent levels 1000 times lower than peak levels after 600 mg clindamycin phosphate given intravenously or 300 mg of clindamycin hydrochloride given orally.

Clindamycin phosphate was detected in the urine of all 6 patients in amounts from less than 1 ng/ml to 53 ng/ml. Since the total cumulative dose of clindamycin phosphate applied to the skin was 60 mg, the percent of dose recovered in the urine was 0.156% (range 0.08 to 0.34%).

The penetration of clindamycin into comedones has been demonstrated. When 9 patients were treated with topical 1% clindamycin phosphate twice daily for 16 weeks, all patients had one or more comedones containing clindamycin bioactivity. In addition, quantitative cultures of acne comedones were performed on 5 clindamycin and 8 vehicle-treated patients. Clindamycin produced significantly reduced *P. acnes* colony counts at weeks 6, 12 and 14.

Thirty-five *P. acnes* isolates from the clindamycin-treated patients were tested for their clindamycin susceptibility. No stepwise increases in MIC were encountered in specimens collected over the observation period (16 weeks treatment, 12 weeks post-treatment). The largest MIC observed was 0.39 $\mu$g/ml.

Four patients treated with topical clindamycin phosphate developed resistant strains of *Staphylococcus aureus* and *enterococci* during treatment. Two thirds of these strains had disappeared 8 weeks after treatment. All strains of *Propionibacteria acnes* were sensitive to clindamycin and remained so through an 8 week treatment period.

There were no changes in the colonic flora when patients received topical clindamycin phosphate treatment. No increased resistance to clindamycin was detected in the colon.

A comparative irritancy study showed retinoic acid most irritating, followed by 1% clindamycin hydrochloride and benzoyl peroxide. No irritancy was found for clindamycin phosphate or a 3% sulfur cream.

An evaluation for potential to cause allergic contact dermatitis was performed in 102 patients using 1% and 3% clindamycin phosphate. On rechallenge all were negative.

Clindamycin phosphate 1% solution was tested for sensitization potential by the Draize test with the addition of ultraviolet irradiation. No evidence of photoallergic or allergic contact sensitization was found in any subject.
MICROBIOLOGY

Clindamycin phosphate is inactive in vitro but in vivo hydrolysis converts this compound to the antibacterially active clindamycin. Clindamycin has been shown to have in vitro activity against isolates of Propionibacterium acne.

TOXICOLOGY

Animal Studies
A 1% solution of clindamycin phosphate was applied once a day and a 3% solution was applied three times a day to rats for 21 days. No inflammation, hyperplasia, parakeratosis, hemorrhage or edema was noted in the treated area of the skin. In the 3% solution study, females grew in weight slightly more, had slightly lower leukocyte and heterophil counts, and had a lower proportion of liver: body weight (21 day) when compared to control animals. Bioactivity was present in serum immediately after last application in the 1% and 3% studies, however in the 3% study, bioactivity was present in the skin, urine and trace amounts in the long bones 5 days after the last application. There was no difference in absorption between animals with intact or abraded skin.

A 1% clindamycin hydrochloride topical solution was applied daily to dogs for 21 days. There was no skin damage and no evidence of absorption in the dog.

A 3% clindamycin hydrochloride solution was applied three-times-a-day to pigs for 21 days. There was no skin irritation and five days post-therapy, there was residual bioactivity present in the treated skin, which was largely confined to the epidermis.

Reproduction and Development Toxicity
Oral and subcutaneous reproductive toxicity studies in rats and rabbits revealed no evidence of impaired fertility or harm to the fetus due to clindamycin, except at doses that caused maternal toxicity.
In oral embryo fetal development studies in rats and subcutaneous embryo fetal development studies in rats and rabbits, no developmental toxicity was observed except at doses that produced maternal toxicity.

Mutagenicity
Clindamycin phosphate did not show evidence of mutagenicity when tested in the AMES ASSAY (Salmonella/Microsome Test) or the Micronucleus Test.

Ocular Application
Rats were administered 1% clindamycin hydrochloride or phosphate formulations to the eyes for 20 days. There was no evidence of ocular irritation or inflammation. A single administration of 1% clindamycin hydrochloride to the eyes of rabbit produced mild to moderate irritation similar to that for the vehicle control.
REFERENCES


8. Puhvel SM. Effects of treatment with erythromycin 1.5% topical solution or clindamycin phosphate 1% topical solution on P. acnes counts and free fatty acid levels. Cutis 1983;31:339-42.


ABOUT THIS MEDICATION

What the medication is used for:
DALACIN T is used for the treatment of pimples (Acne Vulgaris).

What it does:
DALACIN T provides clindamycin, which is an antibacterial. Clindamycin works by preventing growth of bacteria associated with acne.

When it should not be used:
Do not use DALACIN T if:
- You have a history of hypersensitivity (allergies) to preparations including clindamycin or lincomycin or to any ingredient in the formulation or component of the container (see What the non-medicinal ingredients are).
- You have a history of inflammatory bowel disease (including regional enteritis and ulcerative colitis, or a history of antibiotic-associated colitis (inflamed bowel).

What the medicinal ingredient is:
Clindamycin phosphate

What the important nonmedicinal ingredients are:
isopropyl alcohol (500 mg) (50.0% w/v), propylene glycol (50 mg) (5.0% w/v).

What dosage forms it comes in:
Each ml of DALACIN T solution contains 10 mg of clindamycin (as clindamycin phosphate). DALACIN T is a clear colourless solution available in 30 and 60 mL bottles. A separate applicator and cap for placement into the bottle is provided.

WARNINGS AND PRECAUTIONS

DALACIN T is for external use only. Not for oral, intravaginal or ophthalmic use. Avoid contact with eyes, mouth, lips, other mucous membranes, or areas of broken skin.

BEFORE you USE DALACIN T talk to your doctor or pharmacist if:
Safety and effectiveness in pediatric patients under the age of 12 have not been established.
- you are pregnant, or planning to become pregnant. Safety for use in pregnancy has not been established.
- you are breast-feeding or plan to breast-feed while using DALACIN T as the active substance in this medicine may be passed into breast milk. Your doctor will decide if DALACIN T is suitable for you.

Flammable
DALACIN T solution is flammable. Do not smoke or be near a flame during and immediately after the application of DALACIN T.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all your medicines, including vitamin supplements, herbal remedies or homeopathic remedies, including those you have bought yourself. Some medicines can affect the way this medicine works. These include:
- Erythromycin
- Aminoglycosides (gentamycin)
- Muscle relaxants (neuromuscular blocking agent) used in surgery

Using another topical product that contains alcohol such as cleansers, medicated soaps or cosmetics in the same area as DALACIN T may lead to additional skin dryness or irritation.

PROPER USE OF THIS MEDICATION

Apply a thin film of DALACIN T to the skin affected by acne twice daily.

Before applying this medicine
Wash the area to be treated thoroughly but gently with warm water and bland soap. Unless skin is oily, washing 2 or 3 times a day with non-medicinal cleanser is enough. Rinse well and pat dry.
Wait 30 minutes after shaving, before applying the medicine because the alcohol in it may irritate freshly shaven skin.

To use the applicator:
1. Remove cap from bottle and discard.
2. Firmly press applicator into bottle.
3. Seal firmly by tightening domed-cap.

The pharmacist may have assembled the bottle for you, in which case the applicator top will already be attached to the bottle.

To apply DALACIN T
Apply the medicine directly to the skin using the applicator top. The bottle should be tilted and pressed firmly against the skin using a dabbing rather than a rolling motion. Reducing the pressure will decrease the flow.
A thin film of the medicine is to be applied to the whole area affected by acne, not just to the pimples themselves. To avoid getting medication into the eyes, nose, or mouth, the medicine should be spread away from these areas when applied.
If the medicine does get in the eyes, they must be washed out immediately but carefully, using large amounts of cool tap water. If the eyes still burn or are painful, get medical help immediately.

After applying this medicine do not wash your face for at least two hours.

You should wash your hands after applying this medicine.

Your condition may get better after 8 weeks if you respond well to the treatment. If you need more than 12 weeks treatment, talk to your doctor.

Watch for signs of increased dryness or irritation if you use the medicine with other topical products.

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

Missed Dose:
If you should forget to apply your medicine on your skin at the usual time, apply it when you remember, unless it is almost time for your next application, in which case wait and apply at the next application time. The dose should not be doubled to make up for a missed dose.

Overdose:
In case of drug overdose, particularly accidental oral ingestion, contact your doctor, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Absorption of isopropyl alcohol into the body should be considered a possibility if there has been accidental ingestion.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

DALACIN T may cause side effects. These include the following:
- Dry or scaly skin
- Peeling of skin
- Stinging or burning feeling
- Eye pain
- Itching, hives, redness and gastrointestinal symptoms such as indigestion and gas.

Contact your doctor immediately if you develop any of the following side effects:
- Skin rash, itching, redness or other signs or irritation not present before using this medicine.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking DALACIN T and contact your healthcare professional immediately.

<table>
<thead>
<tr>
<th>Serious side effects and what to do about them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom / effect</td>
</tr>
<tr>
<td>Very Common</td>
</tr>
<tr>
<td>Rash, Skin reactions: itching, peeling, dry, sunburn</td>
</tr>
<tr>
<td>Common</td>
</tr>
<tr>
<td>Diarrhea</td>
</tr>
<tr>
<td>Rare</td>
</tr>
<tr>
<td>Nausea, abdominal pain</td>
</tr>
<tr>
<td>Vomiting</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects while taking DALACIN T, contact your doctor or pharmacist.

HOW TO STORE IT

Keep all medications out of the reach and sight of children.
Store at room temperature 15°C to 30°C.
Store away from heat and direct light. Do not freeze.
Store the bottle in an upright fashion.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:  Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.
MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.pfizer.ca
or by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

Last revised: 09 February 2015