

PART III: PATIENT MEDICATION INFORMATION**Pr DALACIN® T
clindamycin phosphate topical solution USP**

Read this carefully before you start taking DALACIN T and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about DALACIN T.

Antibacterial drugs like DALACIN T treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, DALACIN T should be taken exactly as directed. Misuse or overuse of DALACIN T could lead to the growth of bacteria that will not be killed by DALACIN T (resistance). This means that DALACIN T may not work for you in the future. Do not share your medicine.

What DALACIN T is used for?

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

How does DALACIN T work?

DALACIN T contains the agent clindamycin which helps prevent the growth of bacteria that are found with acne. This helps reduce acne.

What are the ingredients in DALACIN T?

Medicinal ingredients: Clindamycin phosphate.

Non-medicinal ingredients: isopropyl alcohol (500 mg) (50.0% w/v), propylene glycol (50 mg) (5.0% w/v).

DALACIN T comes in the following dosage forms:

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.

Do not use DALACIN T if:

- You are allergic (hypersensitive) to
 - Clindamycin
 - Lincomycin
 - Other ingredients in the product (see list of non-medicinal ingredients)
- You have a history of
 - regional enteritis
 - ulcerative colitis (inflamed bowel)
 - inflamed bowel (antibiotic-associated colitis)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DALACIN T. Talk about any health conditions or problems you may have, including if you:

- you are pregnant, or planning to become pregnant.
- you are breast-feeding or plan to breast-feed while using DALACIN T.

Other warnings you should know about:

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.

Should not be used in children under the age of 12.

Flammable

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

Breast-feeding

If you are breast-feeding or planning to breast-feed while taking DALACIN T, talk to your doctor. DALACIN T may pass through your breast milk to your baby. Your doctor will decide if you should take this medicine while breast-feeding. If your doctor has told you that you can take DALACIN T while breast-feeding, monitor your baby for possible side effects such as: diarrhea, mouth infection (thrush: white lesions in your baby's mouth), diaper rash or blood in their stool. If your baby shows any signs, talk to your doctor and to your baby's doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DALACIN T:

- Erythromycin
- Aminoglycosides (gentamycin)
- Muscle relaxants (neuromuscular blocking agent) used in surgery

If you use another product that contains alcohol, such as:

- cleansers
- medicated soaps
- cosmetics

It may dry or irritate your skin.

Usual dose

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

How to take DALACIN T:**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.

Rinse well and pat dry.

Wait 30 minutes after shaving. The alcohol in it may irritate freshly shaven skin.

To attach the applicator top:

1. Remove cap from bottle and discard.
2. Firmly press applicator top into the bottle.
3. Tighten the applicator cap firmly.

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

To apply DALACIN T

Apply directly to the skin using the applicator top. Tilt the bottle and press firmly against the skin using a dabbing motion.

Reducing the pressure will decrease the flow.

A thin film is to be applied to the whole area affected by acne, not just to the pimples themselves. Avoid contact with eyes, nose or mouth.

If you get it in the eyes, carefully wash out your eyes right away with a lot of cool tap water. If your eyes still burn or hurt, 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.

Overdose:

If you think you have taken too much **DALACIN T**, contact your healthcare professional, 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.

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.

What are possible side effects from using DALACIN T?

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.

Call your doctor right away if you develop any of the following:

- Skin rash
- Itching

- Redness or other signs of irritation not present before using this medicine.

You may have *Clostridium difficile colitis* (bowel inflammation), if you have:

- severe bloody or watery diarrhea with or without:
 - abdominal pain
 - tenderness

If this occurs, stop taking the medicine and contact your doctor right away.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Rash, Skin reactions: itching, peeling, dry, sunburn		√	
COMMON Diarrhea		√	
RARE Nausea, abdominal pain Vomiting		√ √	
NOT KNOWN <i>Clostridium difficile colitis</i> (bowel inflammation) with symptoms such as severe or persistent diarrhea, abdominal pain, nausea and vomiting.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your health care professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator
1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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.

If you want more information about DALACIN T:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website (<http://www.pfizer.ca>), or by calling Pfizer Canada ULC at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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