PATIENT MEDICATION INFORMATION:

clindamycin phosphate Antibiotic Pfizer

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE: 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 is DALACIN T 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.

Nonmedicinal 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 Nonmedicinal 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 are pregnant, or planning to become pregnant.
- you are breast-feeding or plan to breast-feed while using DALACIN T. Your doctor will decide if DALACIN
 T is suitable for you.

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.

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.

How to use 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 is enough.

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.

Usual dose:

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

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 the 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 C. difficile colitis (bowel inflammation), if you have:

- · severe bloody or watery diarrhea with or without:
 - o 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			
	Talk to your healthcare professional		Stop taking drug and get
Symptom/effect	Only if severe	In all cases	immediate medical help
VERY COMMON		'	'
Rash Skin reactions: itching, peeling, dry, sunburn		√	
COMMON			
Diarrhea		√	
RARE		l	1
Nausea, abdominal pain		V	
Vomiting		√	
NOT KNOWN		l	1
C. difficile colitis (bowel inflammation) with symptoms such severe or persistent diarrhea, abdominal pain, nausea and vomiting.			V

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 healthcare professional.

Reporting Side Effects

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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/healthcanada.html), the manufacturer's website (http://www.pfizer.ca), or by calling Pfizer Canada Inc. at 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

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