DALACIN® T 1% Topical Lotion

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Dalacin T?

Dalacin T contains the active ingredient clindamycin phosphate. Dalacin T is used on the skin to help treat acne.

For more information, see Section <u>1. Why am I using</u> <u>Dalacin T?</u> in the full CMI.

2. What should I know before I use Dalacin T?

Do not use if you have ever had an allergic reaction to Dalacin T, clindamycin, lincomycin, methyl hydroxybenzoate, or any of the ingredients listed at the end of the CMI; have or have previously had inflammatory bowel disease or antibiotic-associated colitis.

Talk to your doctor if you have had any bowel problems, atopic dermatitis, or any other medical conditions, take any other medicines, or are

pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Dalacin T? in the full CMI.

3. What if I am taking/using other medicines?

Some medicines may interfere with Dalacin T and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Dalacin T?

- Shake the bottle immediately before use. Apply a thin layer twice a day to the affected areas of the skin.
- Avoid contact with sensitive surfaces such as the eyes, eyelids, ears, lips, inside the mouth, inside the nose, penis, vagina, and anus.

More instructions can be found in Section <u>4. How do I</u> <u>use Dalacin T?</u> in the full CMI.

5. What should I know while using Dalacin T?

Things you should do

 Remind any doctor, dentist, or pharmacist you visit that you are using Dalacin T.

If you get severe diarrhoea tell your doctor or seek medical treatment immediately. Do this even if it occurs several weeks after you have stopped using Dalacin T.

Things you should not do

- Do not stop using this medicine without talking to your doctor.
- Do not give your medicine

	to anyone else, even if they have the same condition as you.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Dalacin T affects you.
Drinking alcohol	No information available.
Looking after your medicine	 Store it in a cool dry place below 25°C, away from moisture, heat, or sunlight. Keep it where young children

cannot reach it.

For more information, see Section <u>5. What should I know while using Dalacin T?</u> in the full CMI.

6. Are there any side effects?

Nausea; diarrhoea; irritated, dry, oily, or itchy skin; skin rash, redness, burning sensation; stomach pain.

More rarely: cold/flu, cough, sore throat, stuffy nose/congestion; indigestion/heartburn, bloating, excessive wind; constipation; dizziness; headache; eye pain/irritation; nausea, vomiting; skin flaking, discolouration or blisters; weight loss; hair loss; change in taste/voice; numbness of face; nosebleed; coloured tongue; swelling of hands/feet/ankles.

There are rare but serious side effects that may need immediate medical attention: severe diarrhoea which may have blood and mucus; bleeding/bruising more easily than normal; signs of an allergic reaction; discomfort when urinating; rapid heartbeat, chest tightness.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

DALACIN® T 1% Topical Lotion

Active ingredient(s): [Clindamycin phosphate]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dalacin T. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dalacin T.

Where to find information in this leaflet:

- 1. Why am I using Dalacin T?
- 2. What should I know before I use Dalacin T?
- 3. What if I am taking/using other medicines?
- 4. How do I use Dalacin T?
- 5. What should I know while using Dalacin T?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Dalacin T?

Dalacin T contains the active ingredient clindamycin phosphate. Dalacin T is an antibiotic lotion used on the skin to treat acne.

Dalacin T works by decreasing acne lesions and/or stopping the growth of skin bacteria that cause acne.

Ask your doctor if you have any questions about why Dalacin T has been prescribed for you. Your doctor may have prescribed Dalacin T for another reason.

This medicine is available only with a doctor's prescription.

Dalacin T is not addictive.

2. What should I know before I take use Dalacin T?

Warnings

You must tell your doctor, and should not use Dalacin T if you:

- have ever had an allergic reaction to clindamycin or lincomycin or methyl hydroxybenzoates or any of the ingredients listed at the end of this leaflet.
- have, or have previously had inflammatory bowel disease, or antibiotic-associated colitis (severe diarrhoea associated with the use of antibiotics).

You should not be using this medicine if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

 have bowel disease or any gastrointestinal (stomach or gut) problems

- have atopic dermatitis
- take any medicines for any other conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Talk to your doctor if you are:

- pregnant or intend to become pregnant.
- breastfeeding or intend to breastfeed.

Dalacin T may pass into breastmilk and may have effects on your baby. Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking/using other medicines?

Tell your doctor or pharmacist if you are taking/using any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Dalacin T and affect how it works including:

- erythromycin, a medicine used to treat bacterial infections.
- opiates, medicines used to treat strong pain.
- diphenoxylate with atropine used for diarrhoea.

some medicines that may be used during surgery.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dalacin T.

4. How do I use Dalacin T?

How much to use and how to use it

Shake the bottle immediately before use. Apply a thin layer twice a day to the affected areas of the skin.

Avoid contact with sensitive surfaces such as the eyes, eyelids, ears, lips, inside the mouth, inside the nose, penis, vagina and anus. If you are not sure what to do and how to use it, ask your doctor or pharmacist.

How long to use it

Continue using Dalacin T for as long as your doctor recommends. Treatment of acne may take up to 12 weeks before full improvement is seen. However, results from the use of this medicine have not been demonstrated beyond 12 weeks. If you are not sure how long you should be using Dalacin T, check with your doctor.

If you forget to use Dalacin T

Apply Dalacin T lotion when you remember, unless it is almost time for your next application, in which case wait and apply at the next application time.

If you use too much Dalacin T

If you use too much Dalacin T, you may experience unwanted side effects.

If Dalacin T is Swallowed

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Dalacin T?

Things you should do

 For external use only. Avoid contact with sensitive surfaces such as the eyes, eyelids, ears, lips,

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- inside the mouth, inside the nose, penis, vagina and anus.
- Tell your doctor or pharmacist if you do not feel well while using Dalacin T.
- Tell your doctor immediately if you suffer mild diarrhoea, or seek immediate emergency medical attention if you experience severe diarrhoea which may contain blood. Do this even if it occurs several weeks after stopping Dalacin T.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Dalacin T.
- Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.
- If you become pregnant or plan to breastfeed while using Dalacin T, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

- Do not stop using this medicine without talking to your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use Dalacin T to treat any other illnesses unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dalacin T affects you.

Drinking alcohol

No information available.

Looking after your medicine

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window-sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

When to discard your medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
 Symptoms of cold/flu, cough, sore throat, stuffy nose, congestion dizziness headache eye pain or irritation. nausea, vomiting constipation coloured tongue stomach pain, indigestion, heartburn, bloating, passing excessive wind skin problems such as 	Speak to your doctor if you have any of these side effects and they worry you.
flaking, itching, burning, dryness, irritation,	

Side effects	What to do
oiliness, discoloration, blisters	
weight loss	
change in taste or voice	
 hair loss or small pimples around hair follicles that may be itchy or sore 	
 swelling of the hands, ankles or feet 	
numbness of the face	
nosebleed	
broken bones	

Serious side effects

Serious side effects	What to do
 severe diarrhoea which may have blood and mucus, stomach pain, fever bleeding or bruising more easily than normal signs of allergy (rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
shortness of breath, wheezing or trouble breathing) discomfort when urinating, change in urinary color/frequency/ urgency. rapid heartbeat, chest tightness	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dalacin T contains

Active ingredient	clindamycin phosphate
(main ingredient)	
Other ingredients	cetostearyl alcohol
(inactive ingredients)	glycerol
	glyceryl monostearate
	isostearyl alcohol
	methyl hydroxybenzoate
	mono- and di- glycerides
	potassium hydroxide
	purified water
	sodium lauroyl sarcosinate
	stearic acid
Potential allergens	methyl hydroxybenzoate

Do not take this medicine if you are allergic to any of these ingredients.

What Dalacin T looks like

Dalacin T is a white to off-white lotion. It is available in a 60 mL bottle.

AUST R 67060 - DALACIN T 1% clindamycin 10mg/mL (as phosphate) lotion bottle

Who distributes Dalacin T

Pfizer Australia Pty Ltd

Level 17, 151 Clarence Street SYDNEY NSW 2000

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2024.

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