

Package leaflet: Information for the patient

Dalacin® T Topical Lotion 10 mg/ml Cutaneous Emulsion clindamycin (as phosphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dalacin T is and what it is used for
2. What you need to know before you use Dalacin T
3. How to use Dalacin T
4. Possible side effects
5. How to store Dalacin T
6. Contents of the pack and other information

1. What Dalacin T is and what it is used for

Dalacin T contains an antibiotic called clindamycin phosphate and comes as a lotion. It is used on the skin to treat acne.

2. What you need to know before you use Dalacin T

Do not use Dalacin T:

- If you are allergic (hypersensitive) to clindamycin, lincomycin or to any of the other ingredients of this medicine (listed in section 6).
- If you have or have suffered from inflammatory bowel disease including bowel inflammation following treatment with antibiotics (antibiotic-associated colitis).
- If you are taking an antibiotic to treat an infection.

Warnings and precautions

If you develop severe or prolonged or bloody diarrhoea when using Dalacin T stop using the lotion and **tell your doctor immediately**. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with antibiotics.

Take care when using the lotion around your mouth as it has an unpleasant taste.

Other medicines and Dalacin T

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, or if you are using any other medicines on your skin, including medicines obtained without a prescription, particularly the following:

- muscle relaxants used during operations.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Breast-feeding

Tell your doctor if you are breast-feeding as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin T is appropriate for you.

Dalacin T should not be used on your chest if breast-feeding.

Driving and using machines

No effects on the ability to drive or use machines have been seen with Dalacin T.

Dalacin T Lotion contains cetostearyl alcohol and methyl parahydroxybenzoate

Cetostearyl alcohol may cause local skin reactions such as contact dermatitis (an inflammation of the skin). Methyl parahydroxybenzoate may cause allergic reactions that can be delayed.

3. How to use Dalacin T

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose:

Usually, you should use this medicine twice a day. Shake the bottle well before use. Wash the affected area and put on a thin film of lotion. The lotion bottle has a dispensing cap. Gently rub the lotion over your skin.

Always close the cap after use.

If you forget to apply Dalacin T

Do not worry if you miss one or two applications; just carry on as soon as you remember. Do not apply a double dose to make up for a forgotten dose.

If you stop using Dalacin T

Do not stop using Dalacin T as soon as your acne starts to get better. Ask your doctor when you should stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you develop severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation

Other side effects that have been seen with Dalacin T

Very common: may affect more than 1 in 10 people

- skin irritation (may cause symptoms such as burning, itching, peeling)
- hives
- dryness of skin

Common: may affect up to 1 in 10 people

- seborrhoea: a condition of the sebaceous glands in which there is an overproduction of sebum resulting in oily skin

Frequency not known, but may also occur

- severe acne (also known as Gram-negative folliculitis)
- pain in the eye
- stomach ache
- inflammation of the skin caused by contact with irritants or allergens
- gastrointestinal disorder (include symptoms such as stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dalacin T

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Shake immediately before use.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information**What Dalacin T contains**

The active substance is clindamycin. Each ml of Dalacin T lotion contains 10 mg of clindamycin. The other ingredients are: glycerol, sodium lauroyl sarcosinate, stearic acid, tegin (self emulsifying glyceryl monostearate), cetostearyl alcohol (see section 2), isostearyl alcohol, methyl parahydroxybenzoate (E218) (see section 2) and purified water.

What Dalacin T looks like and contents of the pack

Dalacin T Lotion is a white to off-white aqueous emulsion in a plastic bottle with a dispensing cap. Bottle contains 30 ml of Dalacin T Topical Lotion.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Manufacturer:

Pfizer Service Company BV
Hoge Wei 10
Zaventem 1930
Belgium

Company Contact Address:

For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland
Telephone 1800 633 363.

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