

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

DALACIN® T TOPICAL LOTION
CLINDAMYCIN 1%w/v TOPICAL LOTION
(clindamycin phosphate)

Your medicine is known as the above names but will be referred to as Dalacin T throughout the following leaflet.

This product is also available as a topical solution.

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 your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to 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 possible 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 the active substance clindamycin phosphate. It is an anti-infective used on the skin for the treatment of acne in adults.

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

Do not use Dalacin T

- if you are allergic to clindamycin, lincomycin or any of the other ingredients of this medicine (listed in section 6).
- if you have a history of inflammatory bowel disease or antibiotic - associated colitis.

Warnings and precautions

Talk to your doctor or pharmacist before using Dalacin T if you have diarrhoea or usually get diarrhoea when you take antibiotics. If you develop severe or prolonged or bloody diarrhoea during or after using Dalacin T **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with antibiotics.

Take care when using Dalacin T 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.

Tell your doctor if you are using any skin treatments that contain benzoyl peroxide. These medicines should not be used at the same time as Dalacin T.

If you are going to hospital for a surgical procedure, tell your doctor and/or anaesthetist if you are taking neuromuscular blocking agents (drugs that cause paralysis of muscle).

Pregnancy and breast-feeding

Pregnancy

Dalacin T should be used during pregnancy only if clearly needed.

Breast-feeding

Tell your doctor if you will be breastfeeding 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. If you continue to take Dalacin T, you should stop breast-feeding.

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

Driving and using machines

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

Dalacin T contains cetostearyl alcohol and methyl parahydroxybenzoate

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Methyl parahydroxybenzoate may cause allergic reactions (possibly 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.

Usually, you should use this medicine twice a day. Shake the bottle well before use and wash the affected area before applying the lotion. Apply a thin film of the lotion to the affected area by gently rubbing it into your skin. You may use a cotton pad for this, or you can use your fingers.

Wash and dry your hands before and after using the lotion. The Dalacin T bottle has a dispensing cap. Always replace 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.

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 or pseudomembranous colitis.

Side effects that have been seen with Dalacin T are:

Very common: may affect more than 1 in 10 people

- Skin irritation (may cause symptoms such as burning, itching, peeling), hives, dryness of skin,
- Hives,
- A disease of the sebaceous glands resulting in an oily coating, crusts, or scales on the skin (seborrhoea)

Uncommon: may affect up to 1 in 100 people

- Gastrointestinal disorder (may cause symptoms such as diarrhoea, and nausea)

Frequency not known, but may also occur

- Infection of the hair follicles in the skin (also known as folliculitis),
- Stinging of the eye,
- Pain in the eye,
- Stomach ache,
- Inflammation of the skin caused by contact with irritants or allergens

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dalacin T

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 25°C.
- Replace cap tightly after use.
- Do not use after the expiry date printed on the carton label or bottle.
- If the lotion becomes discolored or show any other signs of deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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 phosphate. Each ml contains clindamycin phosphate equivalent to 10 mg of clindamycin.

The other ingredients are glycerol, sodium lauroyl sarcosinate, stearic acid, glyceryl monostearate, cetostearyl alcohol, isostearyl alcohol, methyl hydroxybenzoate and water.

What Dalacin T looks like and contents of the pack

Dalacin T is a white to off-white aqueous emulsion.

Dalacin T is available in bottle of 30 ml.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S & M Medical Ltd, Chemilines House, Alperton Lane, Wembley, Middlesex HA0 1DX.

Manufacturer

Dalacin T is manufactured by Pfizer Service Company BVBA, Hoge Wei 10, 1930 Zaventem, Belgium.

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