

Package leaflet: Information for the patient

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Dalacin® T Topical Solution/Topical Lotion

Dalacin® T Topical Solution/Topical Lotion

Clindamycin phosphate

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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 an antibiotic called clindamycin phosphate and comes as either a solution or lotion. The solution and the lotion are 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 hypersensitive (allergic) to clindamycin, lincomycin or to 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 **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.

Dalacin T Topical Solution contains alcohol, which can cause burning or irritation of your eyes. Keep it away from your eyes, mouth, and cuts or grazes on your skin. If you get any of these sensitive areas, wash it away with plenty of cool water. Take care when using the lotion or the topical solution around your mouth as they each have an unpleasant taste.

Dalacin T Topical Solution is flammable. Do not use the solution near flames or while you are smoking.

Other medicines and Dalacin T

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 drugs that cause paralysis of muscle (neuromuscular blocking agents).

Pregnancy and breast-feeding**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 will be breast-feeding 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.

Driving and using machines

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

Dalacin T Solution contains propylene glycol

This may cause skin irritation.

Dalacin T Lotion contains cetostearyl alcohol and methyl parahydroxybenzoate

Cetostearyl alcohol may cause local skin reactions such as 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.

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 solution or lotion.

The Dalacin T Solution bottle has an automatic pad dispenser. Gently apply a thin film onto your skin using the pad on the applicator.

The Dalacin T Lotion bottle has a dispensing cap. Wash your hands before and after use and dry them, apply a thin film of the lotion by gently rubbing it into your skin, you may use a cotton pad for this or you can use your fingers. 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 Topical Lotion and Dalacin T Topical Solution 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 or 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 the 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 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.
- 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 phosphate. Each ml of Dalacin T lotion or solution contains 10 mg of clindamycin.

The other ingredients are:

- **Lotion:** glycerol, sodium lauroyl sarcosinate, stearic acid, tegin, cetostearyl alcohol, isostearyl alcohol, methylparaben and water.

- **Solution:** isopropyl alcohol, propylene glycol, hydrochloric acid, sodium hydroxide and 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. Bottles contain 30 ml or 60 ml of Dalacin Topical Lotion.

Dalacin T Solution is a clear colourless solution in a plastic bottle with an automatic pad dispenser and cap. Bottles contain either 30 ml, 50 ml or 60 ml of Dalacin T Solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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