

Package leaflet: Information for the patient

Dalacin® T Topical 10 mg/ml Cutaneous Solution 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 your 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 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
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1. What Dalacin T is and what it is used for

Dalacin T contains an antibiotic called clindamycin phosphate and comes as a solution. 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 solution and **tell your doctor immediately**. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with antibiotics.

Dalacin T 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 Dalacin T Solution on any of these sensitive areas, wash it away with plenty of cool water. Take care when using the Dalacin T Solution around your mouth as it has an unpleasant taste.

Dalacin T 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, 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 Solution contains propylene glycol

This may cause skin irritation.

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 solution. The solution bottle has an automatic pad dispenser. Gently dab the pad onto your skin.

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. 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
- dry 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

Uncommon: may affect up to 1 in 100 people

- gastrointestinal disorder (include symptoms such as stomach pain, heartburn, diarrhoea, constipation, nausea and vomiting)

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

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 HPRA 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 Solution contains 10 mg of clindamycin.

The other ingredients are: isopropyl alcohol, propylene glycol, water, sodium hydroxide (for pH adjustment) and concentrated hydrochloric acid (for pH adjustment).

What Dalacin T looks like and contents of the pack

Dalacin T Solution is a clear colourless solution in a plastic bottle with an automatic pad dispenser and cap. Bottles contain either 30 or 50ml of Dalacin T Solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Manufacturer:

Pfizer Service Company BVBA
Hoge Wei
1930 Zaventem
Belgium

Company Contact Address:

For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland Telephone 1800 633 363.

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