PATIENT INFORMATION LEAFLET

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Dalacin® T Topical Lotion
Clindamycin Phosphate 1% w/v Topical Lotion

(clindamycin phosphate)

Your medicine is available using any one of above names but will be referred to as Dalacin T throughout this leaflet.

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 this medicine, **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 this medicine 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 this medicine 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 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 this medicine 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
- Dry skin
- 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)

Not known: frequency cannot be estimated from the available data
- 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 use Dalacin T after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If your lotion becomes discoloured or shows any sign of deterioration, return to your pharmacist.
- 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 ingredient is Dalacin T is clindamycin phosphate.
Each ml of lotion contains 10mg of clindamycin (as phosphate).
Also contains glycerol, sodium lauryl sarcosinate, glyceryl monostearate, stearic acid, isostearyl alcohol, cetostearyl alcohol, methyl parahydroxybenzoate (E218) and purified water. See section 2 'Dalacin T contains cetostearyl alcohol and methyl parahydroxybenzoate'.

What Dalacin T looks like and contents of the pack
Dalacin T is a white to off-white aqueous emulsion and comes in 30ml plastic bottle with a dispensing cap.

Manufacturer and Product Licence Holder
Manufactured by Pfizer Service Company bvba, Hoge Wei 10, 1930, Zaventem, Belgium and is procured from within the EU by Product Licence holder Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd

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