

CLINIDERM[®] T Gel

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about CLINIDERM T

CLINIDERM T gel is available in 1%/0.025% and 1%/0.05% dosage forms;

CLINIDERM T 1%/0.025%: clindamycin 1 % (as clindamycin phosphate) and tretinoin 0.025%

CLINIDERM T 1%/0.05%: clindamycin 1 % (as clindamycin phosphate) and tretinoin 0.05%

The excipients are: sodium benzoate, propylene glycol, glycerol, carbomer, sodium hydroxide, purified water.

CLINIDERM T is for topical use.

CLINIDERM T is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

The effect of CLINIDERM T is due to the antibacterial activity of Clindamycin and to the effect of tretinoin, which increases the turnover of epidermal cells and loosens the cells compacted to form comedones.

The way to use CLINIDERM T

Use CLINIDERM T as directed by your doctor.

CLINIDERM T should be applied once daily in the evening to the skin where acne lesions appear.

Wash your face thoroughly with mild soap and warm water at bedtime.

After drying the skin, apply a thin layer of the gel over the affected area using fingertips in gentle rubbing motion. Wash your hands afterwards.

Duration of treatment

The duration of treatment should be decided by your doctor.

Therapeutic results will be noticed after several weeks of treatment. Do not be discouraged if you see no immediate improvement. Do not stop treatment at the first signs of improvement.

In case of overdose

An overdose of this medication is unlikely to occur. If medication is applied excessively, no more rapid or better results will be obtained and skin irritation may increase. If you suspect an overdose, irritation develops, or if the gel has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This drug is contra-indicated in the following conditions:

- In case of history of hypersensitivity to clindamycin, lincomycin, or any of the components.
- In patients with regional enteritis, ulcerative colitis, or history of antibiotic-associated colitis.

Precautions

- This medication is for external use only. Avoid contact with the eyes, corners of the nose, mouth, open wounds and all mucous membranes. If contact occurs, rinse thoroughly with water.
- Discontinue the use of the gel and notify your doctor if gastrointestinal symptoms such as diarrhea occur during topical therapy or if irritations or a reaction suggesting sensitivity occur.
- Avoid excessive exposure to sunlight, sunlamp and ultraviolet light while using this medication. Use a sunscreen in the morning and several times daily as needed. Wear protective clothing when exposure to the sun is unavoidable.

Patients with sunburn should not use the product until fully recovered.

Weather extremes, such as wind or cold, also may be irritating to patients under treatment with this gel.

- Do not apply the gel more than once daily because this may irritate your skin.
- Inform your doctor that you are taking this medication before you get general anesthesia.
- Consult your doctor before using this medication in case of pregnancy or lactation.
- Safety and effectiveness of this drug in pediatric patients below the age of 12 years have not been established.

Associations with other medications

Please inform your doctor if you are using any other medication.

Concomitant use with erythromycin-containing products is contra-indicated.

Caution should be taken with the neuromuscular blocking agents.

Avoid products that can increase skin irritation such as abrasive soaps or astringent skin cleansers (perfumed or alcoholic products).

Adverse reactions

The most reported adverse reactions of topical therapy include skin dryness and exfoliation, erythema, itching, burning, and stinging. Sunburn and dermatitis were also reported.

Adverse gastrointestinal effects including diarrhea, and less frequently, colitis have been rarely reported following topical application of products containing clindamycin.

A temporary skin color change may occur.

Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. Do not freeze. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

CLINIDERM T 1%/0.025 % gel, clindamycin 1 % (as clindamycin phosphate) and tretinoin 0.025%, tube of 30 g

CLINIDERM T 1%/0.05 % gel, clindamycin 1 % (as clindamycin phosphate) and tretinoin 0.05%, tube of 30 g

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