

CLINIDERM® 1% Topical 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

CLINIDERM topical gel contains Clindamycin 1% (as clindamycin phosphate).

Other ingredients: methylparaben, carbopol, propylene glycol, sodium hydroxide, purified water.

CLINIDERM is for topical use.

Clindamycin is an antibiotic semisynthetic derivative of lincomycin. Following topical application to the skin, clindamycin phosphate is converted to clindamycin which inhibits the growth of susceptible organisms (primarily *Propionibacterium acnes*) on the surface of the skin by inhibiting bacteria protein synthesis. *Propionibacterium acnes* produce inflammatory mediators that result in papules, pustules, and later, nodulocystic lesions that are typical of inflammatory acne.

CLINIDERM is indicated for topical application in the treatment of acne vulgaris.

The way to use CLINIDERM

Use according to your doctor's instructions.

Apply a thin film of CLINIDERM once or twice daily to the skin where acne lesions appear. Use enough to cover the entire affected area lightly.

The area under treatment should be thoroughly cleansed with a mild soap, and dried, followed by application of the gel in gentle rubbing motion, using fingertips to apply medication. Wash your hands afterwards.

Maintenance therapy is needed to prevent recurrence.

Duration of treatment

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

Skin irritation may develop when this gel is used excessively. If medication is applied excessively, no more rapid or better results will be obtained. If you suspect an overdose, irritations develop or if the gel has been ingested, inform your doctor at once.

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 contraindicated in the following conditions:

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

Precautions

- This medication is for external use only. Avoid contact with the eyes, mouth, open wounds and all mucous membranes. If contact occurs, rinse thoroughly with water.
- This drug should be prescribed with caution in atopic individuals.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. This drug should not be used during lactation.

-Discontinue the use of the gel and notify your doctor if gastrointestinal symptoms such as diarrhea occur during topical therapy with this drug or if a reaction suggesting sensitivity or irritations occur.

- Safety and effectiveness in pediatric patients under the age of 12 have not been established.

Association with other medications

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

Concurrent use of abrasive or medicated soaps or cosmetic products containing alcohol (e.g., astringents, after-shave lotions) may cause a cumulative irritant or drying effect in patients using topical anti-infectives.

Use caution in patients receiving neuromuscular blocking agents.

Adverse reactions

This topical gel is generally well tolerated.

The most reported adverse effects of topical therapy are burning and dryness of the skin, pruritus, irritation, erythema, oiliness, and worsening of acne. Painful skin, scaly rash, and contact dermatitis have been rarely reported.

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

Report to your doctor any signs of adverse reactions.

Storage

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

Pack presentation

CLINIDERM topical gel, clindamycin 1% (as clindamycin phosphate), tube of 30 g

Revision date: 03/2015

CLIG1/003

Manufactured by Mediphar Laboratories- Lebanon