

NAXIDERM®
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 NAXIDERM

NAXIDERM topical gel contains nadifloxacin 1% with the following excipients: sodium metabisulfite, carbomer, monopropylene glycol, sodium hydroxide, and purified water.

NAXIDERM gel is for topical use.

Nadifloxacin is a quinolone antibiotic with a broad spectrum of antibacterial activity against aerobic Gram-positive and aerobic Gram-negative and anaerobic bacteria including *Propionibacterium acnes* and *Staphylococcus epidermidis*.

NAXIDERM topical gel is indicated in the topical treatment of mild or moderate inflammatory forms of acne vulgaris (papulopustular acne, grade I-II).

The way to use NAXIDERM

Use according to your doctor's instructions.

Apply a thin film of NAXIDERM twice daily to the skin where acne lesions appear. The area under treatment should be thoroughly cleansed with a mild soap, and dried, followed by application of the gel. Wash your hands afterwards. To avoid infections, the gel should be applied using a swab.

Duration of treatment

The duration of treatment will be decided by your doctor. Usually, the duration of treatment is up to 8 weeks but can be extended up to a maximum 12 weeks.

In case of overdose

If medication is applied excessively, no more rapid or better results will be obtained and marked redness, or discomfort may occur. 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 contraindicated in case of hypersensitivity to any of the components.

Precautions

- This drug is for external use only. Avoid contact with the eyes and other mucous membranes. If contact occurs wash thoroughly with water.
- This drug should not be applied to damaged skin (cuts and grazes).
- Avoid exposure to sunlight and ultra-violet light while using this medication.
- If a reaction suggesting sensitivity or irritations occur, usage of the medication should be discontinued.
- This drug should not be used under occlusive dressings.

- Consult your doctor before using this medication in case of pregnancy or lactation.
- Safety and effectiveness of this drug in pediatric patients less than 14 years of age have not been established.

Associations with other medications

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

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

Adverse reactions

The most commonly reported adverse reactions are: pruritus, burning sensation, erythema, contact dermatitis, and urticaria.

Skin hypopigmentation has been rarely reported.

Report to your doctor any signs of adverse reactions.

Storage

Store at controlled room temperature (below 30°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

NAXIDERM topical gel, nadifloxacin 1%, tube of 30 g

Issue date: 01/2016

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