CUTIDERMINE [®] 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 CUTIDERMINE

CUTIDERMINE topical gel contains Metronidazole 1% with the following excipients: propylene glycol, ethoxydiglycol, disodium edetate, carbomer, sodium hydroxide and purified water.

CUTIDERMINE is for topical use.

CUTIDERMINE is indicated for the topical treatment of inflammatory lesions of rosacea.

The effect of CUTIDERMINE in rosacea may be due to the antibacterial and/or antiinflammatory effects of Metronidazole.

The way to use CUTIDERMINE

Use according to your doctor's instructions.

- First wash and dry the affected areas of your skin; a gentle cleanser should be used.
- Then, apply a thin layer of the gel, once daily, to the affected areas.
- Rub the gel in well.
- Wash your hands afterwards.
- Appropriate cosmetics may be used after the application of CUTIDERMINE.

Duration of treatment

The duration of treatment will be decided by your doctor. 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. If you suspect an overdose, 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 patients with a history of hypersensitivity to metronidazole or to any of the excipients.

Precautions

- Metronidazole should be administered with caution to patients with central nervous system diseases and with history of blood dyscrasia.
- This medication is for external use only. Avoid contact with the eyes, mouth, and all mucous membranes. If contact occurs, rinse thoroughly with water.
- Inform your doctor if a local irritation develops.
- Avoid excessive exposure to sunlight and ultra-violet light while using this medication.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. A decision should be made whether to discontinue nursing or to discontinue the drug.
- Safety and effectiveness of this drug in pediatric patients have not been established.

Associations with other medications

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

Use caution with oral anticoagulants and alcohol.

Adverse reactions

Reported topical adverse reactions include: skin irritation, dryness, scaling, pruritus, stinging, burning, transient redness, and contact dermatitis.

Other reported adverse reactions include: metallic taste, nausea, and tingling or numbness of extremities.

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

Storage

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children. Do not refrigerate.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack presentation

CUTIDERMINE topical gel, Metronidazole 1%, tube of 30 grams

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CUTG1/001

Manufactured by Mediphar Laboratories -Lebanon