

PATIENT INFORMATION LEAFLET

DERMACUTAN® 0.1% Gel

For Topical Use

Active Substance: 1 g of DERMACUTAN® Gel contains 1 mg of dimethinden maleate.

Excipients: Benzalkonium chloride, disodium EDTA, carbomer, propylene glycol, sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have any additional questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed specifically for you. Do not give it to others.*
- *Even if others have similar symptoms to yours, the medicine may harm them.*
- *While using this medicine, inform your doctor that you are taking it whenever you visit a doctor or hospital.*
- *Follow the instructions in this leaflet exactly. Do not take **higher or lower doses** than the recommended dose for you.*

This Package Leaflet contains:

1. ***What is DERMACUTAN® and what is it used for?***
2. ***What should be considered before using DERMACUTAN® ?***
3. ***How to use DERMACUTAN® ?***
4. ***What are the possible side effects?***
5. ***How to store DERMACUTAN® ?***

1. What is DERMACUTAN® and what is it used for?

DERMACUTAN® is a medication in the form of a colorless and clear gel containing 0.1% (1 mg/g) of dimetinden maleate as its active ingredient.

DERMACUTAN® belongs to a class of drugs known as topical antihistamines and is used to relieve itching caused by allergic skin reactions and various other causes. When applied to the skin, it relieves itching and irritation within minutes.

DERMACUTAN® is available in 30 g tubes.

DERMACUTAN® is used for:

- Itching due to non-inflammatory skin conditions (dermatosis),

- Rash (urticaria),
- Insect bites,
- Sunburns and superficial minor burns.

2. BEFORE USING TERBISIL® PLUS, PLEASE CONSIDER THE FOLLOWING

Do not use DERMACUTAN® in the following cases:

If:

- You are allergic to dimetinden maleate or any of the excipients in DERMACUTAN® (see the list of excipients),
- You are using DERMACUTAN® on large areas of skin in infants and young children, especially if there is peeling or inflammation.

Use DERMACUTAN® with caution in the following cases:

- Do not expose the areas where DERMACUTAN® is applied to the sun for long periods.
- If you have severe itching and/or large wounds, consult your doctor before using

DERMACUTAN®.

- If any of these warnings apply to you, even if they occurred in the past, please consult your doctor.

Use of DERMACUTAN® with food and drink:

There is no known interaction between DERMACUTAN® and food or drink as it is applied topically.

Pregnancy:

Before using this medication, consult your doctor or pharmacist.

If you are pregnant, do not apply DERMACUTAN® to large areas of skin, especially if there is peeling or inflammation.

If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Breastfeeding:

Before using this medication, consult your doctor or pharmacist.

If you are breastfeeding, do not apply DERMACUTAN® to large areas of skin, especially if there is peeling or inflammation.

Do not apply DERMACUTAN® to your nipples.

Driving and using machines:

DERMACUTAN® does not affect your ability to drive or operate machinery.

Important information about some of the excipients in DERMACUTAN®:

If you do not have a sensitivity to the excipients in DERMACUTAN®, no negative effects are expected.

Since DERMACUTAN® contains propylene glycol, it may cause skin irritation.

As DERMACUTAN® contains benzalkonium chloride, it may cause irritant skin reactions.

Use of DERMACUTAN® with other medicines:

If you are currently using or have recently used any prescription or over-the-counter medications, please inform your doctor or pharmacist.

3. How to use DERMACUTAN®?**• Instructions for proper use and dosage/application frequency:**

Unless your doctor advises otherwise, apply 2–4 times a day.

If your symptoms do not improve within a week, consult your doctor.

After the first 3 months of pregnancy, DERMACUTAN® should not be applied to thin, tense, or inflamed skin, and should be used with caution.

• Route and method of application:

Apply DERMACUTAN® to the affected area of skin.

• Use in different age groups:**Use in children:**

Do not apply DERMACUTAN® to large skin areas in infants and young children, especially if there is peeling or inflammation.

• Special usage conditions:

There are no special usage conditions.

If you feel the effect of DERMACUTAN® is too strong or too weak, speak with your doctor or pharmacist.

If you have used more DERMACUTAN® than you should:

If you have used more DERMACUTAN® than required, consult your doctor or pharmacist.

If you forget to use DERMACUTAN®:

Do not use a double dose to make up for the forgotten dose.

Effects when stopping DERMACUTAN® treatment:

None.

4. Possible side effects

Like all medicines, DERMACUTAN® may cause side effects in people who are sensitive to any of its ingredients.

The following terms and frequency levels are used to describe possible side effects:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), unknown (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:

Rare: Mild dryness of the skin, mild burning sensation

Very rare: Allergic skin reactions

If you experience any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting Side Effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storing DERMACUTAN®

Store DERMACUTAN® in a place out of the sight and reach of children, in its original packaging.

Store DERMACUTAN® at room temperature below 25°C.

Use in accordance with the expiration date.

Do not use DERMACUTAN® after the expiration date on the packaging.

Do not dispose of expired or unused medicine in the trash! Dispose of it through the collection system designated by the Ministry of Environment and Urbanization.

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]