

SUMMARY OF PRIDUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DERMACUTAN 0.1% GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 g of DERMACUTAN® contains 1 mg of dimetindene maleate.

Excipients:

Benzalkonium chloride	0.1 mg
Propylene glycol	150 mg

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel: Colorless, clear gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DERMACUTAN® is used for pruritus (itching) associated with dermatoses, urticaria, insect bites, sunburn, and superficial mild burns.

4.2 Posology and method of administration

Dosage/frequency and duration of application:

Should not be used without consulting a doctor.

Unless otherwise recommended by your doctor, apply 2-4 times a day.

It should not be applied to thin, taut, or inflamed skin surfaces after the first three months of pregnancy – use with caution.

Method of administration:

DERMACUTAN® is for external use only.

Additional information on special populations:

Renal/Liver impairment: The use of DERMACUTAN® in individuals with kidney or liver impairment has not been studied.

Pediatric population:

DERMACUTAN® should not be used on large areas of skin in infants and young children, especially if peeling or inflammation is present.

Geriatric population:

The use of DERMACUTAN® in elderly individuals has not been studied.

4.3 Contraindications

DERMACUTAN® is contraindicated in individuals known to be hypersensitive to dimetindene maleate or any of the excipients contained in the product.

4.4 Special warnings and precautions for use

- Areas where DERMACUTAN® is applied should not be exposed to sunlight for long periods.
- DERMACUTAN® should be avoided on large skin areas of infants and young children, especially if peeling or inflammation is present.
- DERMACUTAN® contains propylene glycol, which may cause skin irritation.
- DERMACUTAN® contains benzalkonium chloride, which may cause irritant skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.6 Pregnancy and lactation

General advice:

Pregnancy category: B.

Women of childbearing potential/Contraception:

There is no clinical data available regarding exposure to dimetindene maleate during pregnancy.

Animal studies do not show direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, birth, or postnatal development (see section 5.3).

Pregnancy

DERMACUTAN® should be used with caution during pregnancy.

It should not be applied to large areas of skin during pregnancy, particularly if peeling or inflammation is present.

Lactation

Systemic exposure to dimetindene maleate during lactation is negligible, so no effects on the breastfed child are expected.

DERMACUTAN® should be used with caution during breastfeeding.

It should not be applied to large areas of skin, especially if peeling or inflammation is present. DERMACUTAN® should not be applied to the nipple during breastfeeding.

Fertility

Preclinical safety studies have shown that dimetindene maleate does not affect fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

DERMACUTAN® does not affect the ability to drive or use machines.

4.8 Undesirable effects

The frequency of adverse effects observed in clinical studies is presented below according to the MedDRA classification:

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 available data).

Skin and subcutaneous tissue disorders:

Rare: Mild dryness of the skin, mild burning sensation

Very rare: Allergic skin reactions

Reporting of suspected adverse reactions

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.

4.9 Overdose and treatment

There have been no reported cases of overdose with dimetindene maleate. However, when dimetindene maleate is applied to a very large surface area or damaged skin, or if accidentally ingested in large amounts, it may cause some symptoms typical of an overdose of H1 antihistamines: CNS depression with drowsiness (especially in adults), Excitement, ataxia, hallucinations, tonic-clonic spasms, mydriasis, dry mouth, facial flushing, urinary retention, and fever due to CNS stimulation and antimuscarinic effects (especially in children). Hypotension may also occur.

Treatment:

There is no specific antidote for an overdose of antihistamines. In case of oral overdose, general emergency treatment should be applied: Activated charcoal, saline laxatives, and if necessary, supportive measures for general circulation and respiration. Stimulants should not be used. Vasopressors may be used to treat hypotension.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Topical antihistamines

ATC code: D04AA13

Mechanism of action:

Dimetindene maleate is a potent histamine antagonist at H1 receptor sites. It has a high affinity for binding to these receptors. It significantly reduces the hyperpermeability of capillaries associated with acute hypersensitivity reactions. When applied topically, dimetindene maleate also demonstrates local anesthetic properties.

DERMACUTAN® Gel is effective for itching caused by various conditions and quickly relieves itching and irritation. The gel base facilitates the passage of the active substance through the skin.

5.2 Pharmacokinetic properties**General characteristics:**

The clear, colorless hydrogel base reveals the full properties of the active substance and facilitates its penetration into the skin.

DERMACUTAN® rapidly penetrates the skin and exerts its antihistaminic effect within a few minutes. The maximum effect is achieved 1–4 hours after application.

In healthy volunteers, after topical application, the systemic bioavailability of dimetindene maleate is approximately 10% of the applied dose.

5.3 Preclinical safety data

No teratogenic effects were observed in rats and rabbits. Dimetindene did not affect fertility or prenatal and postnatal development of offspring in rats at doses 250 times higher than the human dose. No mutagenic effects were observed in various in vitro and in vivo studies.

6. PHARMACEUTICAL PROPERTIES**6.1 List of excipients**

Benzalkonium chloride

Disodium EDTA

Carbomer

Propylene glycol

Sodium hydroxide

Deionized water

6.2 Incompatibilities

No known incompatibilities.

6.3 Shelf life

24 months

6.4 Special storage precautions

Store below 25°C at room temperature.

6.5 Nature and contents of the packaging

In a carton, in a white HDPE capped aluminum tube, 30 g.

6.6 Disposal of unused medicinal products and other special precautions

Unused products or waste materials should be disposed of in accordance with the "Regulation on the Control of Medicinal Products" and the "Regulations on the Control of Packaging Waste."

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

[To be completed nationally]

9. INITIAL MARKETING AUTHORIZATION DATE / MARKETING AUTHORIZATION RENEWAL DATE

[To be completed nationally]

10. PACKAGE LEAFLET RENEWAL DATE

[To be completed nationally]