

Patient Information Leaflet (PIL)

Fenistil

0.1% Gel

For External Use only.

Read this entire leaflet carefully before you start using this medicine because it contains important information for you.

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

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1. What is contained in Fenistil Gel?

1 g of Fenistil Gel contains 1 mg of dimetindene maleate as active ingredient.

Excipients with known effect: Propylene glycol and benzalkonium chloride solution 50%

Other excipients: Carbomer, Sodium Hydroxide, Disodium edetate, purified water.

2. What is Fenistil Gel and what it is used for?

Fenistil gel is effective against skin disorders with itching, for example, insect bites, mild localised sunburn, small surface burns, and localised allergic dermatoses. The gel base facilitates the penetration of the active ingredient into the skin, in this way the itching and irritation is rapidly relieved (after a few minutes).

3. What you need to know before you use Fenistil gel?

a. Do not use Fenistil Gel in cases of:

- Hypersensitivity to the active ingredient dimetindene maleate or to any of the excipients listed above
- The product cannot be used as a treatment for known allergies to insect bites (systemic pharmaceutical forms are available for this purpose).

b. Warnings and precautions

- Do not give the product to children under 2 years of age without a medical prescription.
- Avoid applying over large areas, especially in infants and young children.
- Avoid prolonged exposure to the sun of the areas treated.

Fenistil gel contains:

- Propylene glycol which may cause mild, localized skin irritation.
- Benzalkonium chloride which is irritant, and may cause skin reactions.

c. Pregnancy and breast-feeding

Pregnancy

Animal studies with dimetindene do not show teratogenic potential nor do they indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

During pregnancy, Fenistil should not be applied to large, burned or inflamed areas of the skin.

Breast-feeding

The same pregnancy precaution applies to nursing mothers. Moreover, the product should not be applied to the nipples during lactation.

d. Driving and using machines

Fenistil topical formulations have no or negligible influence on the ability to drive or use machines.

4. How to use Fenistil Gel?

In adults and children over 2 years old: Apply Fenistil 2 to 4 times a day on the areas to be treated in a thin layer and massage lightly.

In children less than 2 years old: Fenistil gel can only be used under medical prescription.

Overdose

Accidental swallowing of a considerable amount of topical dimetindene maleate might induce some symptoms characteristic of overdosage with H₁ antihistamines: CNS depression with dizziness (mainly in adults), CNS stimulation and antimuscarinic effects (especially in children), including

excitement, ataxia, hallucinations, tonic-clonic spasms, mydriasis, dry mouth, flushed face, urinary retention and fever. Hypotension may also occur.

Treatment of Overdose

There is no specific antidote for overdose with antihistamines; the usual emergency assistance must be undertaken, including, in case of ingestion: activated charcoal, saline laxative and usual cardio-respiratory supportive measures if necessary. Stimulants should not be used; vasopressors may be used to treat hypotension.

5. Possible side effects

The most commonly reported adverse effects are transient and mild skin reactions in the area of application.

Adverse effects are listed based on organ class and frequency and are listed below. The frequencies are indicated as follows: 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 ($< 1/10,000$).

Skin disorders

Uncommon: Skin dryness, burning sensation.

Post-marketing experience

Skin disorders: Very rare cases of allergic dermatitis have been observed.

Interaction

No interaction studies have been performed;

6. How to store Fenistil Gel?

Do not store above 30°C

Do not use this medicine after the expiry date which is stated on the carton, Blister. The expiry date refers to the last day of that month.

This date applies even if the package is open. Keep out of the reach and sight of children.



Manufactured by:

GSK Consumer Healthcare SARL, Nyon, Switzerland.

MAH: GSK Consumer Healthcare Schweiz AG, Switzerland.

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This is a Medicament

- a. Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- b. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- c. The doctor and the pharmacist are the experts in medicines, their benefits and their risks
- d. Do not by yourself interrupt the period of treatment prescribed
- e. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists