PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Fenistil Gel 0.1% w/w

Dimethindene Maleate 0.1% w/w

Inactive ingredients and allergens in the preparation – see section 6 and section 2 under the title "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

Rash, itch, noninflammatory skin diseases, burns, insect bites, allergic skin inflammation and eczema.

Therapeutic class: anti-histamines

Fenistil Gel neutralizes the effect of histamine, one of the substances that is released during the allergic reaction. When in contact with the skin, Fenistil Gel relieves the itchiness that is caused by the allergic reaction. In addition, Fenistil Gel has a local anesthetic property. Fenistil Gel is a water-based gel and it allows the active ingredient to quickly penetrate well into the skin (within a few minutes) to relieve irritated and itchy skin.

2. Before using the medicine

Do not use this medicine

- If you are sensitive (allergic) to the active ingredient dimethindene maleate or to any of the other ingredients the medicine Fenistil Gel contains, as listed in section 6 of the leaflet.
- If there is a known allergy to insect bites.

Special warnings regarding the use of the medicine

Before treatment with Fenistil Gel, inform the doctor: if you have another disease, if you are allergic, if you are already taking or using other oral or topical medicines (even if self-treating!).

Additional warnings:

- Avoid applying on extensive areas, on open wounds, on extensive skin lesions or on damaged skin (such as burns), especially in small children and infants.
- Avoid prolonged exposure of the treated areas to the sun.
- Consult the doctor in case of significant itchiness or extended lesions.
- Consult the doctor if the symptoms continue for more than 7 days.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Pregnancy and breastfeeding

During pregnancy and breastfeeding, apply Fenistil Gel cautiously, and do not apply on extensive, chafed or inflamed areas of the skin.

Do not apply the gel on the nipples while breastfeeding.

Driving and operating machinery

Fenistil Gel has no effect or negligible effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

Fenistil Gel contains propylene glycol at a concentration of 150 mg/gram: propylene glycol may cause skin irritation.

Fenistil Gel contains benzalkonium chloride at a concentration of 0.05 mg/gram: benzalkonium chloride may cause skin irritation. If you are breastfeeding, do not apply the preparation on the chest, as the substance may pass into the breastmilk.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The generally accepted dosage is:
Adults and children:
Apply a thin layer 2-4 times per day on the affected area and massage gently.
Do not exceed the recommended dose.

Duration of treatment
Do not use Fenistil Gel for more than 7 days in a row without consulting the doctor.

Do not swallow. For external use only.

If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Fenistil Gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Stop using and consult a doctor if an allergic reaction appears on the skin, including rash and itchiness. This is a very rare side effect that appears in less than one user out of 10,000.
Uncommon side effects – side effects that occur in 1-10 users out of 1,000: skin dryness or burning sensation.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.
Storage conditions:
Store below 25°C.

6. Additional information

- In addition to the active ingredient, the medicine also contains:
  Purified Water, Propylene Glycol, Sodium Hydroxide Solution, Carbomer, Disodium edetate, Benzalkonium Chloride
- What does the medicine look like and what are the contents of the package?
  Transparent to yellowish and almost odorless gel.
  Package: aluminum tube closed with a plastic cap.
  Size of the package: 30 grams or 100 grams.
  Not all package sizes may be marketed.
- Marketing authorization holder and address: GSK Consumer Healthcare Israel Ltd., P.O. Box 3256, Petah Tikva
- Name and address of the manufacturer: GSK Consumer Healthcare SARL, Nyon, Switzerland.
- The leaflet was revised in March 2023 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 133-24-24020