PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed without a doctor's prescription

Fenistil Gel

Dimethindene Maleate 0.1% w/w
*Inactive and allergenic ingredients in the preparation - see Section 6

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
You must use the medicine in the correct manner. Consult the pharmacist if you need further information. Refer to the doctor if symptoms of the illness worsen or do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rash, itching, noninflammatory skin diseases, burns, insect bites, allergic dermatitis and eczema.
Therapeutic group: antihistamines

2. BEFORE USING THE MEDICINE

Do not use the medicine
- If you are sensitive (allergic) to the active ingredient dimethindene maleate or to any of the additional ingredients contained in Fenistil Gel, as listed in section 6 of this leaflet.
- When there is a known allergy to insect bites.
- On open or inflamed wounds, skin inflammations with mucosal membranes or fluid on their surface, or near the eyes, especially in children and infants.

Special warnings regarding use of this medicine
- Avoid applying on extensive areas, especially in small children and infants.
- Avoid prolonged exposure of the treated areas to the sun.
- Consult the doctor in case of significant itching or enlarged lesions.
- Consult the doctor if the symptoms persist for more than seven days.
- Fenistil Gel contains propylene glycol and therefore may cause localized skin irritation.
- Tell the doctor if you have another disease, if you are allergic, especially to other medicines, if you are already taking other oral or topical medicines (even if self-treating!).

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

Pregnancy and breastfeeding
During pregnancy and when breastfeeding, apply Fenistil Gel with caution and do not apply to extensive, burned or inflamed areas of the skin.
Do not apply the gel to the nipples when breastfeeding.

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

Important information about some of the ingredients in this medicine
Fenistil Gel contains propylene glycol and benzalkonium chloride, and therefore may cause localized skin irritations.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.
The usual dosage is generally:
Adults and children:
Apply a thin layer 2-4 times a day on the affected area and gently massage.
Do not exceed the recommended dose.
Do not swallow. For external use only.
Use the medicine as explained in the leaflet or as instructed by your doctor. If you feel that the effect of the medicine is too weak or too strong, inform the doctor or pharmacist.
If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
- Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
- If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Fenistil Gel may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
Common side effects (occur in 1-10 in 1000 patients): dry skin or burning sensation.
Rare side effects (occur in 1-10 in 10,000 patients): allergic skin reactions, including skin rash and itching.
In such a case, stop treatment and consult the doctor or pharmacist.
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 can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.
Do not store above 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Purified Water, Propylene Glycol, Sodium Hydroxide Solution, Carbomer, Disodium edetate, Benzalkonium Chloride
- What the medicine looks like and the contents of the package:
  A clear to yellowish and practically odorless gel.
  Package: an aluminum tube with a polyethylene cap.
  Package size: 30 grams and 100 grams.
  Not all package sizes are sold.
- License holder and address: GSK CONSUMER HEALTHCARE ISRAEL LTD., P.O.B. 3256, Petach-Tikva
- Manufacturer and address: GSK Consumer Healthcare S.A., Nyon, Switzerland.
- This leaflet was checked and approved by the Ministry of Health in: June 2018 (M.C: 2.7.2018)
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  133-24-24020

FenGel PT v2