

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

The medicine is dispensed with a doctor's prescription only

Fenistil Drops 1 mg/ml

Active ingredient and its quantity in a dosage unit:

Each 1 ml contains: Dimethindene Maleate 1 mg/ml (each drop contains: 0.05 mg).

For a list of inactive ingredients and allergens in the preparation – please 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.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. This medicine is not intended for children under the age of one month.

1. What is the medicine intended for?

Anti-pruritic, anti-histamine and anti-allergic.

Therapeutic class: the medicine belongs to a group of preparations that bind to the histamine H1 receptor.

Fenistil Drops inhibits the action of histamine, which is one of the substances released during allergic reactions. Fenistil Drops relieves itch and skin irritation caused by allergic reactions, reduces edema (a pathological accumulation of fluids in the skin or in the mucous membranes) and relieves symptoms of allergic rhinitis, such as runny nose and watery eyes as well as sneezing.

2. Before using the medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains (see section 6).
- In babies under 1 month of age, especially in preterm infants.

Special warnings regarding the use of the medicine

Before treatment with Fenistil Drops, inform the doctor if you have:

- Glaucoma
- Urinary retention (e.g., enlarged prostate)
- Epilepsy
- Chronic obstructive pulmonary disease (COPD) or another disease

The elderly:

A doctor should be consulted before starting treatment with the medicine, since side effects such as restlessness or tiredness may occur.

Children and adolescents:

In infants one month to one year old, Fenistil Drops should be used only with a doctor's recommendation. Do not exceed the recommended dose. The sedative effect may be accompanied by sleep apneas. Anti-histamines may cause agitated moods, especially in children and the elderly.

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.

Especially if you are taking:

- Antidepressants (MAO inhibitors or tricyclic antidepressants)
- Anticholinergic agents, such as: bronchodilators (medicines prescribed for treatment of asthma or bronchospasm), gastrointestinal spasmolytics (medicines for spasms in the stomach or abdomen), medicines for dilating the pupil of the eye, urinary spasmolytics (medicines for treatment of urinary incontinence symptoms or overactive bladder)
- Central nervous system depressants (e.g.: sedatives or sleep medicines)
- Anti-epileptic medicines
- Opiate analgesics (potent pain relievers)
- Antihistamines (medicines prescribed for cough, colds or allergies)
- Antiemetic medicines
- Procarbazine (a medicine for treatment of certain types of cancer)
- Scopolamine (medicines for preventing feeling of nausea)
- In the case of alcohol consumption during treatment

Use of the medicine and alcohol consumption

As with other antihistamines, Fenistil Drops may enhance the effect of alcohol.

Pregnancy and breastfeeding

Do not use Fenistil Drops if you are pregnant, unless a doctor instructs you to. Using Fenistil Drops while breastfeeding is not recommended. If you are pregnant or breastfeeding, if you think you might be pregnant or if you are planning to become pregnant, consult with your doctor before using this medicine.

Driving and operating machinery

Caution should be exercised when driving or operating dangerous machinery while using the medicine, since the medicine can affect reactions and the ability to drive or operate machinery. Children should be warned to be careful when riding a bicycle or playing near a road etc.

Important information about some of the ingredients of the medicine

Fenistil Drops contains propylene glycol at a concentration of 100 mg/ml (20 drops).

Fenistil Drops contains benzoic acid at a concentration of 1 mg/ml (20 drops). May worsen jaundice (yellowing of the skin and eyes) in newborns (up to 4 weeks of age).

Fenistil Drops contains less than 23 mg (1 mmol) of sodium in each 1 ml (20 drops), and is therefore considered sodium-free.

Inform your doctor or pharmacist if:

- You have any other disease
- You have hypersensitivities (allergies)
- You are taking other medicines (including non-prescription medicines)

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

Adults and children over the age of 12 years:

20-40 drops, 3 times a day.

Children:

In small children from 1 month to 1 year old, Fenistil Drops should be used only on a doctor's recommendation.

The generally accepted daily dosage is:

2 drops per kg body weight per day, divided into 3 doses.

Age/weight	Dosage in drops
1 month – 1 year / 4.5 – 15 kg	3 – 10 drops, 3 times a day
1 – 3 years / 15 – 22.5 kg	10 – 15 drops, 3 times a day
3 – 12 years / 22.5 – 30 kg	15 – 20 drops, 3 times a day

The doctor will determine the optimal dosage.

Fenistil Drops is not resistant to high temperatures. The drops may be poured into a warm feeding bottle at the last moment before feeding. Babies fed with a spoon may be given undiluted drops in a spoon; they are palatable.

Duration of treatment

Do not use Fenistil Drops for more than 14 consecutive days without an explicit instruction from the doctor.

Do not exceed the recommended dose.

If you accidentally took a higher dose, contact your doctor or pharmacist immediately. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the appointed time, take a dose as soon as you remember, unless less than two hours remain until the time of the next dose. In that case, skip the forgotten dose and continue at the same intervals you started with. Do not take a double dose to compensate for the missed dose!

Follow the treatment as recommended by the doctor.

If you feel that the effect of the medicine is too weak or too strong, inform your doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose every time you take the 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 Drops 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 taking Fenistil Drops and refer to your doctor immediately if one or more of the following symptoms occur, as they can be a sign of an allergic reaction:

- Difficulty breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Significant skin itching accompanied by red rash or blisters, muscle cramps

These side effects occur very rarely (in less than one patient out of 10,000). Other side effects are usually moderate and transient. They mostly occur in the beginning of the treatment.

Very common side effects – side effects that occur in more than one out of ten users: tiredness.

Common side effects – side effects that occur in 1-10 out of 100 users: sleepiness, nervousness.

Rare side effects – side effects that occur in 1-10 out of 10,000 users: agitation, headache, dizziness, gastrointestinal disturbances such as: vomiting, dry mouth or throat.

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. The expiry date refers to the last day of that month.

Storage conditions:

- Store at room temperature (15-25°C)
- Protect from light
- The medicine may be used for up to six months after first opening

6. Additional information

- In addition to the active ingredient the medicine also contains:
Purified Water, Propylene Glycol, Disodium Phosphate Dodecahydrate, Citric Acid Monohydrate, Benzoic Acid, Disodium Edetate, Saccharin Sodium.
- What does the medicine look like and what are the contents of the package? Fenistil Drops is a clear and transparent solution.

Available in 20 ml glass bottles.

Marketing authorization holder and importer:

Haleon CH Israel Ltd., P.O.B. 3256, Petach Tikva.

- Registration number of the medicine in the national drug registry of the Ministry of Health: 034-23-22255

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