

Fenistil

Drops

Only for Oral Use

Read this entire leaflet carefully before you starts 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 has 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.

In this leaflet

1. What is contained in Fenistil Drops?
2. What is Fenistil Drops and what is it used for?
3. What you need to know before you use Fenistil Drops
4. How to use Fenistil Drops
5. Possible side effects
6. How to store Fenistil Drops

1. What is contained in Fenistil Drops?

1 ml (=20drops) of Fenistil drops contains 1 mg of dimetindene maleate as active ingredient.
Excipients: Propylene glycol, Disodium phosphate dodecahydrate, citric acid monohydrate, benzoic acid, disodium edetate, saccharin sodium, purified water.

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

Fenistil drops are indicated for symptomatic treatment of allergic disorders: urticaria, upper respiratory tract allergies such as hay fever and rhinitis independent of the season, food and medicinal product allergies.

- Pruritus of various origins, except for cholestatic pruritus.
- Pruritus in eruptive diseases such as chicken pox and Insect bites.

It is used as adjuvant treatment in case of eczemas and other pruritic dermatoses of allergic origin.

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

a. Do not use Fenistil Drops in cases of:

- Hypersensitivity to the active substance, dimetindene maleate or to any of the excipients listed above.
- Infants less than one month of age, particularly premature infants.

b. Warnings and precautions:

As with other antihistamines, caution is recommended in case of administration in patients with glaucoma, or bladder neck obstruction (e.g. prostatic hypertrophy) and chronic obstructive pulmonary disease.

Caution should be taken if used by epilepsy patients.

Antihistamines may cause agitation in young children and elderly patients.

Use in young children from 1 month to 1 year of age: Caution is recommended in case of administration of any antihistamine in infants aged less than 1 year: the sedative effect may be associated with episodes of sleep apnea.

Fenistil should be administered in infants one month to one year of age only on medical advice and for a strict medical indication to antihistamine treatment. The recommended dose should not be exceeded.

Use with caution in elderly patients, as this age group is more susceptible to adverse reactions such as agitation and fatigue. Use in confused elderly patients should be avoided. The recommended dose and duration of use must not be exceeded without a doctor's approval.

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.
Safety for use during human pregnancy has not been established. Fenistil should be used in pregnancy only if strictly indicated.

Breast-Feeding

It is reasonable to assume that dimetindene may be secreted in breast milk. The use of Fenistil is not recommended during breast feeding.

d. Driving and using machines

Like other antihistamines, Fenistil may diminish mental alertness in some patients. Caution should therefore be observed while driving, operating machines or performing other tasks requiring alertness.

4. How to use Fenistil Drops?

Adults and adolescents over 12 years of age:

The daily recommended dose is 3 to 6 mg of dimetindene maleate per day divided into 3 doses; this corresponds to:

Drops 1 mg/mL: 20-40 drops, 3x per day.

In patients with a tendency to drowsiness, it is recommended to prescribe 40 drops before bedtime and 20 drops in the morning at breakfast.

In children:

In small children from 1 month to 1 year of age, Fenistil drops should only be used according to a doctor's recommendations and upon strict medical indication for antihistamines. The recommended dose should not be exceeded.

Caution should be used when administering drops to children under 1 year of age. The sedative effect may be associated with episodes of sleep apnea. The recommended daily dose is 0.1 mg/kg of body weight per day (this corresponds to 2 drops per kg of body weight per day, divided into 3 doses). The usual daily doses for children from 1 month to 12 years of age and based on body weight, are therefore the following:

Age/Weight	Dose in mg	Dose in drops
1 month to 1 year/4.5-15 kg	0.15-0.5 mg three times per day	3-10 drops three times per day
1-3 years/15-22.5 kg	0.5-0.75 mg three times per day	10-15 drops three times per day
3-12 years/22.5-30 kg	0.75-1 mg three times per day	15-20 drops three times per day

20 drops = 1 mL = 1 mg of dimetindene maleate.

1 drop = 0.05 mg of dimetindene maleate.

Fenistil drops cannot withstand high temperatures; before feeding pour them directly into a warm feeding bottle. If the baby is already eating with a spoon, give the drops in a teaspoon; their taste is pleasant. Do not take oral drops for more than 14 days without consulting a doctor.

Overdose

The signs and symptoms of overdose by H1 antihistamines include: depression of the central nervous system accompanied by drowsiness (primarily in adults), stimulation of the central nervous system and antimuscarinic effects (in particular in children) including excitation, tachycardia, ataxia, hallucinations, tonic or clonic seizures, mydriasis, dry mouth, facial redness, urinary retention and fever. Later, hypotension, coma and cardio-respiratory collapse may occur.

There is no specific antidote in case of overdose by antihistamines. Treatment must be consistent with the clinical symptoms or Tox Info Suisse guidelines

5. Possible side effects:

Undesirable effects include drowsiness especially at the beginning of the treatment. In very rare instances, allergic reactions may occur.

Adverse reactions are listed below by system organ class and frequency:

Immune system disorder

Very rare: Anaphylactic reactions including face oedema, pharyngeal oedema, rash, muscle spasms and dyspnoea

Psychiatric disorder

Rare: Agitation

Nervous system disorder

Very common: Fatigue

Common: Somnolence, nervousness

Rare: Headache, dizziness

Gastrointestinal disorder

Rare: Gastrointestinal upset, nausea, dry mouth/dry throat

Interaction

The concurrent use of two or more drugs that depress the CNS may be expected to result in increased CNS depression. This may have undesirable and even life-threatening consequences.

These drugs include opioid analgesics, anticonvulsants, tricyclic antidepressants and MAO inhibitors, antihistamines, antiemetics, antipsychotics, anxiolytics, hypnotics, scopolamine, and alcohol.

Tricyclic antidepressants and anticholinergic drugs (e.g. bronchodilators, gastrointestinal antispasmodics, mydriatics, urological antimuscarinics) may have an additive antimuscarinic effect with antihistamines, increasing the risk of aggravating glaucoma or urinary retention.

In order to reduce the risks of CNS depression or possible potentiation, caution must be exercised when administering procarbazine and antihistamines concomitantly.

6. How to store Fenistil Drops?

Do not store above 30°C.

Protect from light

Keep the bottle in the outer carton

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.

Keep out of the reach and sight of children.

Presentation:

Fenistil drops :20ml

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 medication.

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

