

Fenistil® Tablets/Drops

NOVARTIS CONSUMER HEALTH

What is Fenistil and when is it used?

Fenistil counteracts the effects of histamine, a substance released during allergic reactions.

Fenistil soothes itching and skin irritations caused by allergic reactions, reduces swelling (pathologic accumulation of liquid in skin or in mucous membranes) and relieves the symptoms of allergic rhinitis such as a running nose, watering eyes and sneezing.

Fenistil is indicated in the case of:

- allergic skin conditions: itching due to various causes (except for itching due to jaundice), eczema and other skin conditions causing itching, urticaria, itching associated with diseases that cause rashes and/or spots such as chicken pox; insect bites;
- allergic conditions involving the upper respiratory tract: hay fever and other allergic rhinitis;
- the treatment of symptoms caused by food and drug allergies.

When should Fenistil not be used?

You must not use Fenistil if you are allergic to one of its components. Fenistil must not be used in newborn babies less than 1 month old, especially premature babies.

What precautions must be taken when taking Fenistil?

Please inform your doctor or pharmacist if:

- you suffer from glaucoma, urinary retention (for example prostatic hypertrophy), chronic obstructive pulmonary disease or from another condition;
- you are allergic, particularly to other drugs;
- you are taking an antidepressant (MAO inhibitor or tricyclic antidepressant), an anticholinergic (drugs for abdominal or stomach spasms), a central nervous system depressor (such as tranquilisers or sleeping pills) or other medications used internally or externally (even self-prescribed!)

The use of Fenistil coated tablets or drops can lead to a drop in concentration; caution is vital when driving a vehicle or carrying out tasks which require concentration (for example operating machinery).

Like other antihistamines, Fenistil can increase the effects of alcohol.

Drops: consult your doctor before giving Fenistil drops to a child of less than 1 year old.

Can Fenistil be taken during pregnancy and while breastfeeding?

You should not take Fenistil if you are pregnant or if you are breastfeeding, unless your doctor has prescribed it for you.

How to use Fenistil?

Adults and children over 12 years old:

Usual daily dose:

Drops: 1 mg/ml: 20-40 drops, 3 times daily.

Coated tablets: 1 mg: 1-2 coated tablets, 3 times daily.

Children: Daily doses from 1 month to 12 years:

Age	Drops 1 mg/ml
1 month – 1 year	3- 10 drops, 3 times daily
1- 3 years	10-15 drops, 3 times daily
3-12 years	15- 20 drops, 3 times daily

Your doctor will determine the optimum dose.

Fenistil drops do not withstand temperature excesses.

Pour them into the baby's warm bottle at the last minute.

If the baby is already fed by spoon, administer them undiluted in a coffee spoon; their taste is pleasant.

Please keep to the dose that appears on the packaging or is prescribed by your doctor. If you think that the drug is having either a too weak or, on the contrary, too strong effect, please consult your doctor or pharmacist.

What side effects can Fenistil cause?

Taking Fenistil can cause the following secondary effects: drowsiness, especially at the start of treatment. Dryness of the mouth or throat, nausea, dizziness, agitation, headaches may sometimes occur. In certain exceptional cases, a skin rash and/or swelling have been observed; stop treatment and consult your doctor or pharmacist. If you notice any side effects that are not mentioned in this leaflet, please inform your doctor or your pharmacist of them.

What else should I be aware of?

Drugs should be kept out of the reach of children.

Coated tablets: protect from light, do not store above 30°C.

Drops: protect from light, keep the bottle in the outer carton, do not store above 30°C.

The drug should not be used after the date which appears under the letters "EXP" on the container. For more comprehensive information, consult your doctor or pharmacist who have at their disposal detailed information intended for health professionals.

What does Fenistil contain?

1 coated tablet contains 1 mg of dimetindene maleate.

1 ml of Fenistil drops contains 1 mg of dimetindene maleate; flavouring: sodium saccharine, preservative: benzoic acid (E210), propylene glycol as well as other excipients.

Where can Fenistil be obtained? What packs are available on the market?

In pharmacies without a doctor's prescription.

Pack of 20 coated tablets.

Packs of 20 and 50 ml drops.

Not all of these packs are available in all countries.

Drops:

Holder and Manufacturer
Novartis Consumer Health SA
Nyon, Switzerland

Tablets:

Manufactured by
Novartis Farmacéutica SA
Barberà del Vallès (Barcelona), Spain
for

Novartis Consumer Health SA
Nyon, Switzerland

Information updated: October 2008

E-AR 908115
145574

 NOVARTIS