

Global Labeling**Fenistil**

Coated tablet
Dimetindene maleate 1 mg

Core Patient Information Leaflet (PIL)

Author:	Kiran Chinnalla
Document status:	Final
GLC approval date:	26 Sep 2013, 20 Mar 2014
GLC tracking ID:	2013-Sep-26/02-S, 2014-Mar-20/08b-S
Amendment date:	Not applicable
Effective date:	28 Mar 2014
Next Update date:	March 2017
Number of pages:	7

Property of Novartis Consumer Health
Confidential
May not be used, divulged, published or otherwise disclosed
without the consent of Novartis Consumer Health

Package leaflet: Information for the patient

Fenistil 1 mg Coated tablet

Dimetindene maleate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take 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. See Section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Fenistil Coated tablet is and what it is used for
2. What you need to know before you take Fenistil Coated tablet
3. How to take Fenistil Coated tablet
4. Possible side effects
5. How to store Fenistil Coated tablet
6. Contents of the pack and other information

1 What Fenistil Coated Tablet is and what it is used for

Fenistil contains dimetindene maleate which belongs to a group of medicines called antihistamines, which are used for the relief of symptoms of allergies such as skin rash, itching, hay fever or other allergic forms of rhinitis.

Fenistil counteracts the action of histamine, which is a substance released by the body during allergic reactions. It relieves itching and irritations caused by skin rash, decreases swelling, and relieves the symptoms of allergic rhinitis such as runny nose, sneezing, itching of the nose, and itchy, watery eyes.

How Fenistil works

Fenistil Coated Tablets provide relief for:

- allergic skin rash and itching of various origins: eczema, dermatitis (inflammation of the skin), insect bites, itching caused by chicken pox, urticaria (hives, nettle rash);

- allergic rhinitis: hay fever and other forms of allergic rhinitis (e.g. allergies to house dust, animal fur, feathers, etc.);
- drug and food allergies.

Fenistil may also be prescribed by your doctor for the prevention of allergic reactions during desensitisation therapy.

You must talk to a doctor if you do not feel better or if you feel worse.

2 What you need to know before you take Fenistil

Do not use or take Fenistil Coated Tablet:

- if you are allergic (hypersensitive) to dimetindene maleate or any of the other ingredients of this medicine.
- in children under 3 years of age.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Fenistil Coated Tablet:

- If you have glaucoma
- If you have difficulty urinating due to enlargement of the prostate
- If you have epilepsy.

If any of the above apply, do not take Fenistil Coated Tablet before talking to your doctor.

Other medicines and Fenistil Coated Tablet

You should not take Fenistil Coated Tablet, unless advised by your doctor, if you are taking any of the following medicines:

- an antidepressant,
- anticholinergic drugs such as bronchodilators (medicine used to treat asthma and bronchospasm), gastrointestinal antispasmodics (medicine used to prevent spasms of your stomach or bowels), mydiatics (medicine used to dilate your pupil), urological antispasmodics (medicine used to treat symptoms of urge incontinence and overactive bladder)
- a sedative, a tranquilliser or a sleeping medicine
- an anticonvulsant (medicine for epilepsy)
- opioid pain killers
- antihistamines (medicine for curing common cough , cold and other allergies)
- antiemetic's (medicines used to stop vomiting)
- procarbazine (medicine used to treat certain types of cancers)
- scopolamine (medicine used to prevent travel sickness)
- alcohol

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Fenistil Coated Tablet with alcohol

Like many other antihistamines, Fenistil Coated Tablet may increase the effects of alcohol.

Children and adolescents

You should be aware that in younger children, antihistamines have been reported to possibly produce excitability.

Pregnancy, breast-feeding and fertility

If you are pregnant, do not use Fenistil Coated Tablet unless prescribed by your doctor. Fenistil Coated Tablet is not recommended during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Like many other antihistamines, Fenistil Coated Tablet cause some people to become tired or less alert than they are normally. If this occurs, you should use caution when driving or operating machinery.

Important information about some of the ingredients of Fenistil Coated Tablet

Fenistil Coated Tablet contains:

- **Sucrose and lactose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **Wheat starch.** It is suitable for people with coeliac disease. Patients with wheat allergy (different from coeliac disease) should not take this medicine.

3 How to take Fenistil Coated Tablet

Do not exceed the recommended dose.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children aged 12 years and over:

One or two tablets three times a day.

Children aged 3 to 12 years:

One tablet three times a day maximum.

If you take more Fenistil Coated Tablet than you should

If you may have taken more Fenistil Coated Tablets than you should, talk to a doctor or pharmacist immediately.

If you forget to take Fenistil Coated Tablet

If you miss a dose, take it as soon as you remember, unless it is less than 2 hours to the next dosing time. In this case, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten one that you missed.

4 Possible side effects

Like all medicines, Fenistil Coated Tablets can cause side effects, although not everybody gets them.

STOP using Fenistil Coated Tablet and seek medical help immediately if you experience any of the following symptoms which may be signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps, muscle spasms

These side effects are **very rare** (*may affect up to 1 in 10,000 people*).

Other side effects which may occur are usually mild and transient. More common side effects occur especially at the beginning of the treatment.

Some side effects are very common (*may affect more than 1 in 10 people*)

- tiredness

Some side effects are common (*may affect up to 1 in 10 people*)

- somnolence
- nervousness

Some side effects are rare (*may affect up to 1 in 1,000 people*)

- agitation
- headache, dizziness
- gastrointestinal upset, nausea, dryness of the mouth or throat

Reporting side effects

{To be adapted based on the national regulations}

“If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

<Country>

{Name}

<{Address}

{Town} {Postal code} – Country>

Tel: + {Telephone number}

<Website>

5 How to store Fenistil Coated Tablet

- **Keep this medicine out of the sight and reach of children.**
- Do not use Fenistil Coated Tablet after the expiry date shown on the carton or on the bottles. The expiry date refers to the last day of that month.
- Protect from light, keep the blisters in the original package.
- Storage conditions

{Storage conditions to be completed nationally according to the stability report for the specific climatic zone and national regulations}.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Fenistil Coated Tablet contains

- The active substance of Fenistil Coated Tablets is dimetindene maleate. Each tablet contains 1 mg dimetindene maleate.
- The other ingredients are lactose, talc (E553b), wheat starch, magnesium stearate (E572), acacia (E414), calcium carbonate (E170), titanium dioxide (E171), sucrose, and polyethylene glycol.

Information might differ in some countries.

{To be adapted nationally for local formulations}

What Fenistil Coated Tablet looks like and contents of the pack

Fenistil Coated Tablets are white sugar-coated tablets. They are available in packs of 20, 50 and 100 tablets.

Not all pack sizes may be marketed.

{To be adapted nationally for local formulations}

Marketing Authorization Holder

{Name and address}

<tel>

<fax>

<e-mail>

{To be completed nationally}

Manufacturer

{Name and address}

{To be completed nationally}

This leaflet was last <revised> <approved> on:

<MM/YYYY> <Month YYYY>

{To be completed nationally}