

## Global Labeling

### **Fenistil**

Oral drops, solution

Dimetindene maleate 1 mg/ml

### **Core Patient Information Leaflet (PIL)**

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## Package leaflet: Information for the patient

### Fenistil 1 mg/ml Oral drops, solution

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

## 1 What Fenistil Oral drops, solution is and what it is used for

Fenistil Oral drops, solution 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 provides 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.

## **2 What you need to know before you take Fenistil Oral drops, solution**

### **Do not use or take Fenistil:**

- if you are allergic (hypersensitive) to dimetindene maleate or any of the other ingredients of this medicine.
- in infants less than one month of age, in particular premature infants.

### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Fenistil Oral drops, solution:

- 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 Oral drops, solution before talking to your doctor.

### **Other medicines and Fenistil Oral drops, solution**

You should not take Fenistil Oral drops, solution, unless advised by your doctor, if you are taking any of the following:

- 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 Oral drops, solution with alcohol**

Like many other antihistamines, Fenistil Oral drops, solution 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.

Do not administer Fenistil Oral drops, solution to a baby aged 1 month to 1 year unless prescribed by a doctor. Do not exceed the prescribed dose.

### **Pregnancy, breast-feeding and fertility**

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

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

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Like many other antihistamines, Fenistil Oral drops, solution may 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.

## **3 How to take Fenistil Oral drops, solution**

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.

Do not exceed the recommended dose.

### **Adults and children aged 12 years and over:**

20 to 40 drops three times a day.

### **Children:**

**Infants 1 month to 1 year (*only on medical advice*):** The recommended daily dose is 2 drops per kg bodyweight per day, divided in three intakes, e.g. 6 drops three times a day for an 8-month old infant weighing 9 kg.

**Children aged 1 to 12 years:** The recommended daily dose is 2 drops per kg bodyweight per day, divided in three intakes, e.g. 8 drops three times a day for a 2 year old child weighing 12 kg.

Fenistil Oral drops, solution should not be subjected to high temperatures. The medicine should be added to the baby's bottle immediately prior to feeding, when it is lukewarm. If the baby is spoon-fed, Fenistil Oral drops, solution should be given undiluted in a teaspoon.

### **If you take more Fenistil Oral drops, solution than you should**

If you may have taken more Fenistil Oral drops, solution than you should, talk to a doctor or pharmacist immediately.

### **If you forget to take Fenistil Oral drops, solution**

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 Oral drops, solution can cause side effects, although not everybody gets them.

STOP using Fenistil Oral drops, solution 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 Oral drops, solution**

- **Keep this medicine out of the sight and reach of children.**
- Do not use Fenistil Oral drops, solution 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 bottle 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 Oral drops, solution contains**

The **active substance** of Fenistil Oral drops, solution is dimetindene maleate. 1 ml solution of Fenistil Oral drops, solution contains 1 mg dimetindene maleate.

The **other ingredients** are disodium phosphate dodecahydrate (E339), citric acid monohydrate (E330), benzoic acid (E210), disodium edetate (E386), saccharin sodium (E954), and propylene glycol (E1520).

Information might differ in some countries.

*{To be adapted nationally for local formulations}*

### **What Fenistil Oral drops, solution looks like and contents of the pack**

Fenistil Oral drops, solution is a clear and colorless solution. It is available in bottles of 20 ml and 50 ml.

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}*