
Global Labeling

Fenistil

Cutaneous emulsion (roll-on)
Dimetindene maleate 0.1%

Core Patient Information Leaflet (PIL)

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Package leaflet: Information for the user

Fenistil 0.1% cutaneous emulsion

Dimetindene maleate

Read all of this leaflet carefully because it contains important information for you.

Always use Fenistil cutaneous emulsion exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- 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 7 days.

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1 What Fenistil is and what it is used for

What Fenistil is

Fenistil cutaneous emulsion contains an active ingredient that belongs to a group of medicines called antihistamines.

Fenistil cutaneous emulsion is used for the relief of itching associated with skin reactions like skin rashes, hives, insect bites, sunburns and superficial burns.

How Fenistil works

Fenistil cutaneous emulsion stops the itch by blocking the action of histamine, which is a substance released by the body during allergic reactions. As the cutaneous emulsion penetrates well into the skin, itching and skin irritation are rapidly relieved, within a few minutes. Fenistil cutaneous emulsion also has a local anesthetic effect.

2 What you need to know before you use Fenistil

Do not use Fenistil emulsion if

- you are allergic to dimetindene maleate or any of the other ingredients of this medicine (see Section 6 and end of Section 2). If you are not sure, ask your doctor or pharmacist.

Warnings and precautions:

- Avoid prolonged exposure to the sun of extensively treated areas of the skin.
- Tell your doctor in case of very severe itching or extensive lesions.

If any of these apply to you, do not use Fenistil emulsion.

Children

In infants and small children, do not use on extensive areas of the skin, particularly if raw or inflamed.

Other medicines and Fenistil

Tell your doctor or pharmacist if you are using, or have recently used, any other medicines, including medicines obtained without a medical prescription.

Pregnancy and breast-feeding

During pregnancy and breast-feeding, do not use Fenistil cutaneous emulsion on extensive areas of the skin, especially if raw or inflamed. Do not apply the cutaneous emulsion on the nipples if you are nursing a baby.

Driving and using machines

Application of Fenistil cutaneous emulsion to the skin does not affect your ability to drive or use machines.

Important information about some of the ingredients of Fenistil emulsion

Fenistil cutaneous emulsion contains:

- propylene glycol which may cause mild, localized skin irritation.
- benzalkonium chloride which is irritant, and may cause skin reactions.
- butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eye and mucous membranes.

3 How to use Fenistil

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Apply 2 to 4 times daily to affected area.

Consult your doctor if your symptoms do not improve within one week.

If you have any questions, talk to your doctor or pharmacist before using Fenistil emulsion.

If you use more Fenistil than you should

If you or a child accidentally swallows this medicine, contact your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Fenistil cutaneous emulsion can cause side effects, although not everybody gets them.

Some side effects are of unknown frequency (*frequency cannot be estimated from the available data*)

- dry skin,
- skin burning sensation
- itchy rash

Reporting side effects

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 any side effects directly to the national reporting system via the internet at *{insert link to the relevant 'national reporting system website' - details will be defined at national level}*; alternatively you can report via *{insert alternative ways of reporting – details will be defined at national level}*. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Fenistil

- **Keep this medicine out of the reach and sight of children.**
- Do not use Fenistil after the expiry date which is stated on the carton and bottle.

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

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

6 What is in the pack and further information

What Fenistil contains

The active substance is dimetindene maleate. Each gram of cutaneous emulsion contains 1 mg of dimetindene maleate.

The other ingredients (excipients) are benzalkonium chloride, benzyl alcohol, butylhydroxytoluene, disodium edetate, coco-caprylate/caprate, liquid paraffin, cetomacrogol, carbomer, propylene glycol, sodium hydroxide, and purified water.

{To be completed nationally for local formulations}

What Fenistil looks like and contents of the pack

Fenistil cutaneous emulsion is supplied as a cooling and soothing, easy to spread lotion with moisturizing properties as an 8 ml roll-on bottle. It does not stain clothes.

{To be completed nationally}

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 approved on:

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