

PACKAGE LEAFLET: INFORMATION FOR THE USER

FENISTIL

Gel

(DIMETINDENI MALEAS)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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

1. WHAT FENISTIL IS AND WHAT IS IT USED FOR

What Fenistil is

Fenistil is an antipruritic, anti-allergic product. The active substance contained in the gel is a strong antihistamine. The gel is colourless and almost translucent and its use is accompanied by a pleasantly cooling sensation.

Fenistil is used to alleviate itching with skin diseases that cause itching and urticaria, flea and insect bites, and with skin damage caused by the sun and mild superficial burns.

How Fenistil acts

Fenistil alleviates itching by blocking the effect of histamine, which is a substance that is released in the body on contact with an allergen and causes the development of an allergic reaction. Since the gel penetrates readily to the skin, it rapidly alleviates itching and irritation of the skin within a few minutes. Fenistil also has a local anaesthetic effect.

The product may be used by adults and children aged from 6 months and without a doctor's prescription.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FENISTIL

Do not use Fenistil

- if you are allergic to dimethindene maleate or any of the other ingredients of this medicine (listed in section 6). If you are not sure, ask your doctor or pharmacist.

Warnings and precautions

- Do not expose more extensive areas of skin treated with the product to the sun. In the event of very severe itching or more extensive lesions, contact a doctor.
- If you have any further questions, ask your doctor or pharmacist before you start using Fenistil.

Children: Do not use on more extensive areas of skin in breast-feeding infants and small children, particularly if there are open or unhealed wounds on these areas.

Other medicines and Fenistil

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

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

During pregnancy or while breast-feeding, the product should not be applied to extensive areas of skin, particularly if there are open or unhealed wounds on these areas. During breast-feeding, Fenistil should not be applied to the nipples.

Driving and using machines

Fenistil has no or negligible influence on the capacity to drive and use machines.

Important information about some of the components of Fenistil:

Fenistil contains:

- Benzalkonium-chloride, which is an irritant and may cause skin reactions.
- propylene glycol, which may cause local skin irritation.

3. HOW TO USE FENISTIL

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless your doctor decrees otherwise, rub the product onto the afflicted area of skin 2-4 times a day. During application, do not press on the skin or scratch it. The gel will begin to have an effect after a few minutes and reach a peak in 2-4 hours.

If your symptoms do not improve in a week, or if your child's symptoms do not improve within two days, talk to your doctor.

Do not use the product for longer than 14 days without consulting a doctor.

Use in children (from 6 months of age)

In breast-feeding infants and small children, do not apply the product to more extensive areas of skin (i.e. larger than the area of two child's hands), and especially not to broken skin or skin affected by inflammation.

If you use more Fenistil than you should

In the event of accidental ingestion of the product, especially by a child, you should seek medical aid without delay

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For some side effects there is no known frequency of occurrence (the frequency of occurrence cannot be estimated on the basis of available data)

- dry skin
- a burning sensation on the skin
- allergic skin reactions including rash and itching

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FENISTIL

Store at below 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after the phrase: "Expiry date:". The expiry date refers to the last day of that month.

Do not throw away any 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 contains

- The active substance is dimetindeni maleas
1 gramme of gel contains 1 mg of dimetindeni maleas.
- The excipients are benzalkonium-chloride, disodium edetate dihydrate, carbomer 974 P, sodium hydroxide solution 300 g/l, propylene glycol, purified water

What Fenistil looks like and contents of the pack

Fenistil is a cooling colourless low-fat gel, with no odour. Aluminium tube, PE closure, box

Pack size: 30, 50 and 100 g.

Not all pack sizes may be on the market.

Manufacturer:

Novartis s.r.o., Na Pankráci 1724/129, 140 00 Prague 4, Czech Republic

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