

PACKAGE LEAFLET: INFORMATION FOR THE USER

EXODERIL

1% dermal solution

NAFTIFINI HYDROCHLORIDUM

• 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 Exoderil is and what it is used for
2. What you need to know before you use Exoderil
3. How to use Exoderil
4. Possible side effects
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1. WHAT EXODERIL IS AND WHAT IT IS USED FOR

Exoderil belongs to the group of drugs called dermatologics, antimycotics.

Exoderil is an antiinflammatory dermal solution for dermal administration. The active ingredient is naftifin, effective against fungi, yeasts and moulds. Besides its effect against moulds, naftifin has an antibacterial effect against various gram-positive and gram-negative organisms usually found in connection with fungal disease. The clinical effect of naftifin manifests by a rapid remission of inflammatory symptoms, especially itching.

The medicine is used for the treatment of:

- fungal diseases of the skin and skin folds,
- fungal diseases between the toes,
- fungal diseases of toe nails,
- skin diseases caused by yeasts,
- pityriasis versicolor caused by *Pityrosporon orbiculare*, and mycoses caused by secondary bacterial infection,
- inflammatory skin fungal diseases (with or without itching).

The medicine is especially suitable for the treatment of mycoses of the hairy parts of the head.

The medicine is suitable both for adults and children.

Fungal infections can manifest as reddening, itching, peeling and cracks of skin.

On feet it manifests usually by cracking or scales on the skin, but also by mild oedema, small blisters or suppurating spots. Fungal nail infection (inside or under nails) can be identified according to a change in nail shape, colour and structure. Nails become thicker, lose shine and could spread also to the surrounding nails.

On the body, head, neck, face or arms, it usually appears as circular areas with a red rash, but scaled areas causing itching can also occur. On the head, skin scaling in the form of white scales (dandruff) can also occur on the hairy parts of the head.

Moreover, scaling areas can occur on the skin, or whitening due to pigmentation loss. These areas are visible especially during the summer because the surrounding skin tans normally. This form of disease occurs on the torso, neck or arms and can reoccur after months, especially during hot periods with increased sweating.

If you are not sure about the cause of your disease, please ask your doctor or pharmacist before using the solution.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EXODERIL

Do not use Exoderil:

- if you are allergic to the active substance or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using Exoderil.

The medicine must not come into contact with eyes or open wounds.

Other medicines and Exoderil

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

No interaction of Exoderil with other medicines are known.

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 using this medicine.

Exoderil may be used during pregnancy or breastfeeding only when absolutely necessary.

3. How to use Exoderil

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

The medicine shall be used only for the treatment of skin and nails.

Exoderil can be used for local treatment in a single daily dose due to rapid permeation into the skin and presence in sufficient concentrations in various skin layers.

The solution shall be used once a day to the affected skin and surrounding area after cleaning and drying.

It is recommended to use twice a day for fungal nail infections.

To prevent a recurrence, treatment shall continue for at least 2 weeks after symptoms or problems have disappeared.

The total duration of treatment depends on the extent, location and nature of the disease, and lasts usually 2 to 4 weeks.

Do not use the medicine for longer than 4 weeks without a recommendation from your doctor.

If you take more Exoderil than you should

In case of overdose or unintended ingestion by a child, seek medical advice.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although they do not affect everyone.

The following frequencies are used to assess undesirable effects:

Very common (>1/10)

Common (> 1/100 to <1/10)

Uncommon (> 1/1,000 to <1/100)

Rare (> 1/10,000 to <1/1,000)

Very rare (<1/10000)

Not known (cannot be estimated from the available data)

General disorders and administration site conditions

Not known: feeling of dryness, redness or burning.

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist. 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 EXODERIL

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

Store below 30°C.

Do not use this medicine after the expiry date stated on the label and carton after {EXP}:. 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 EXODERIL CONTAINS

Active ingredient is naftifini hydrochloridum 10 mg in 1 ml solution.

What Exoderil looks like and contents of the pack Package: 10 ml.

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