Unofficial translation of the German package leaflet

Wording of the details intended for the package leaflet

Package leaflet: Information for the user

exoderil gel 10 mg

Naftifine hydrochloride

exoderil® Gel 10 mg

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use 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 after 7 days.

What is in this leaflet

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

1. WHAT EXODERIL GEL IS AND WHAT IT IS USED FOR

exoderil gel is a product for the treatment of fungal infections (antifungal drug).

Intended uses:

Fungal infections of the skin (dermatomycosis), caused by dermatophytes, yeasts, and fungi, as well as mixed infections with bacteria.

Attempted treatment is indicated for fungal infections of the nails (onychomycosis).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE EXODERIL GEL

Do not use exoderil gel:

- if you are allergic to naftifine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using exoderil gel.

In the event of known hypersensitivity to propylene glycol, it is advisable to use a dosage form that does not contain propylene glycol (exoderil cream) instead of exoderil gel.

exoderil gel contains alcohol and therefore should not come into contact with the eyes or be used on mucous membranes. exoderil gel must not be applied to open wounds.

Other medicines and exoderil gel

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

So far, there are no known interactions with the use of exoderil gel.

Pregnancy and breast-feeding

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.

When applied to the skin as described in the dosage instructions, the active ingredient naftifine is only absorbed by the body to a very low extent; therefore, a systemic effect (effect on other organs) is not expected. Nevertheless, the use of exoderil gel during pregnancy and breast-feeding should only take place after careful assessment of the benefits and risks.

exoderil gel contains propylene glycol.

Propylene glycol may cause skin irritation.

3. HOW TO USE EXODERIL GEL

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

exoderil gel is to be applied thinly to the affected areas of skin once a day, preferably at night, and then rubbed in. For fungal infections of the nails it is recommended that the treatment be applied twice daily (morning and evening).

Generally, the symptoms, e.g., itching, improve within a few days. However, it is important to continue treatment for 1-2 weeks after all signs of infection have resolved. Otherwise there is the risk that the fungal infection may come back after a short time.

Longer treatment durations are usually required for fungal nail infections. However, the duration of use should not exceed 6 months. In general, the duration of treatment depends on the organism responsible for the condition, the extent of the disease, and the region of the body that is affected.

If you use more exoderil gel than you should
In the event of overdose, please talk to your doctor if you develop any symptoms.

If you forget to use exoderil gel
Do not use a double quantity to make up for a forgotten application.

If you stop using exoderil gel
The fungal infection may continue to spread or it may come back if you do not use the treatment for long enough.

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

4. POSSIBLE SIDE EFFECTS

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

Very rare (fewer than 1 in 10,000 patients treated)

Hypersensitivity and, usually temporary, local irritation, burning or dryness of the skin

Reporting of 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 side effects directly via the reporting system at the Bundesinstitut für Arzneimittel und Medizinprodukte [German Federal Office for Drugs and Medical Devices (BfArM)], Abt. Pharmakovigilanz [Pharmacovigilance Department], Kurt-Georg-Kiesinger Allee 3, 53175 Bonn, website: http://www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EXODERIL GEL

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 tube and carton after "Expiry date". The expiry date refers to the last day of that month.

Do not store above 25°C or below 2°C.

Note about shelf-life after opening

The gel can be used for 8 weeks after opening.

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 gel contains

The active substance is naftifine hydrochloride.

1 g gel contains:

Naftifine hydrochloride 10 mg

The other ingredients are: sodium edetate (Ph. Eur.); carbomer 104; trometamol; polysorbate 80; isopropyl alcohol (Ph. Eur.), propylene glycol, purified water

What exoderil gel looks like and contents of the pack

Clear, colourless to pale yellow gel

Tubes with 20 g or 50 g gel

Pharmaceutical company and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG
Kuhloweg 37
58638 Iserlohn, Germany
Tel.: +49 2371/937-0
Fax: +49 2371/937-106
www.medice.de
E-mail: info@medice.de

This leaflet was last revised in July 2013.