Package leaflet: Information for the user
OTC medicine*

Exoderil 10 mg/g cream
naftifine hydrochloride

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.

What is in this leaflet

1. What Exoderil is and what it is used for

The active ingredient of Exoderil topical cream is the anti-fungal agent naftifine that acts to eliminate fungi or inhibit their growth and reproduction, depending on the type of the pathogen (fungus). Exoderil easily penetrates the skin and the therapeutic concentrations of the agent will persist in different layers of skin for an extended period of time.

In addition, Exoderil has an anti-inflammatory effect.

Exoderil cream is used to treat fungal infections of the skin caused by dermatophytes and *Candida*, and to treat *Pityriasis versicolor*.

2. What you need to know before you use Exoderil

Do not use Exoderili
- if you are allergic to the active substance 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.
Only use Exoderil cream externally.
When using Exoderil cream, make sure that the medicine does not get into the eye.
Exoderil cream is for topical (cutaneous) use only.

Other medicines and Exoderil
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
No interaction studies have been carried out.

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.

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Fertility
No studies have been carried out on the effect of Exoderil on fertility.

Pregnancy and breast-feeding
There is no or very limited experience in using naftifine in pregnant patients. Animal tests show no direct or indirect harmful effect related to reproductive toxicity.
As a precaution, the use of Exoderil should be avoided during pregnancy and breast-feeding.

Driving and using machines
Exoderil is not known to have any influence on the ability to drive or use machines.

Exoderil cream contains cetyl alcohol, stearyl alcohol and bensyl alcohol
This medicine contains 40 mg of cetyl alcohol and 40 mg of stearyl alcohol per gram of cream, which may cause local skin reactions (eg contact dermatitis).
This medicine contains 10 mg benzyl alcohol per gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Exoderil

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 cream is intended for topical cutaneous use only.
Exoderil is applied 1 time per day.
Carefully clean and dry the treated area and surrounding areas of skin before the application of the medicine.
Apply a thin layer of Exoderil cream on and around the affected area.
After using Exoderil cream, wash your hands, as otherwise, you may transmit the infection to other areas of your body or to other people.

In order to prevent the recurrence of the disease, treatment should be continued for two weeks after clinical healing.
Symptoms of the disease can start receding after several days. Complete healing of the affected area can take up to 4 weeks.

Keep the affected area clean in order to facilitate healing by occasionally washing the affected area and drying carefully, without rubbing the skin. Even though the treated area can become itchy, try to avoid scratching, as this can cause new damage to the skin or propagate the infection.

If you feel that the effect of Exoderil is too strong or too weak, talk to your doctor or pharmacist.

4. Possible side effects

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

The following incidence categories are used for evaluating side effects:
very common (≥ 1/10);
common (≥ 1/100 to < 1/10);
uncommon (≥ 1/1,010 to < 1/100);
rare (≥ 1/10,000 to < 1/1,000);
very rare (< 1/10,000);
unknown (cannot be estimated from available data)

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Skin and subcutaneous tissue disorders
Unknown: contact dermatitis (skin rash or irritation at the site of application), erythema (reddening of the skin)

General disorders and application site reactions
Unknown: dryness, redness, and burning sensation

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 www.ravimiamet.ee. 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.

Do not store at a temperature higher than 30 °C.

After the initial opening, the cream can be stored for up to 4 weeks at 25 °C.

Do not use this medicine after the expiry date which is stated on the package 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 cream contains
- The active ingredient is naftifine hydrochloride. 1 g of cream contains 10 mg of naftifine hydrochloride.
- The other ingredients are sodium chloride, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate (60), isopropyl myristate and purified water.

What Exoderil cream looks like and contents of the pack
White cream in a metal tube.
The tube contains 15 g of cream.

Marketing Authorisation Holder and manufacturers
Marketing Authorisation Holder:
Sandoz GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

Manufacturers:
Sandoz GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

Salutas Pharma GmbH
Lange Goehren 3
D-39171 Osterweddingen
Germany

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
Sandoz d.d. Estonian branch
Pärnu mnt 105
11312 Tallinn
Phone: 6652400

This leaflet was last revised in June 2021.

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Package leaflet: Information for the user
prescription medicine*

Exoderil 10 mg/g cream
naftifine hydrochloride

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

1. What Exoderil is and what it is used for

The active ingredient of Exoderil topical cream is the anti-fungal agent naftifine that acts to eliminate fungi or inhibit their growth and reproduction, depending on the type of the pathogen (fungus). Exoderil easily penetrates the skin and the therapeutic concentrations of the agent will persist in different layers of skin for an extended period of time.

In addition, Exoderil has an anti-inflammatory effect.

Exoderil cream is used to treat fungal infections of the skin caused by dermatophytes and *Candida*, and to treat *Pityriasis versicolor*.

2. What you need to know before you use Exoderil

Do not use Exoderili
- if you are allergic to the active substance 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.
Only use Exoderil cream externally.
When using Exoderil cream, make sure that the medicine does not get into the eye.
Exoderil cream is for topical (cutaneous) use only.

Other medicines and Exoderil
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
No interaction studies have been carried out.

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.

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Fertility
No studies have been carried out on the effect of Exoderil on fertility.

Pregnancy and breast-feeding
There is no or very limited experience in using naftifine in pregnant patients. Animal tests show no direct or indirect harmful effect related to reproductive toxicity.
As a precaution, the use of Exoderil should be avoided during pregnancy and breast-feeding.

Driving and using machines
Exoderil is not known to have any influence on the ability to drive or use machines.

Exoderil cream contains cetyl alcohol, stearyl alcohol and bensyl alcohol
This medicine contains 40 mg of cetyl alcohol and 40 mg of stearyl alcohol per gram of cream, which may cause local skin reactions (eg contact dermatitis).
This medicine contains 10 mg benzyl alcohol per gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Exoderil

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 cream is intended for topical cutaneous use only.
Exoderil is applied 1 time per day.
Carefully clean and dry the treated area and surrounding areas of skin before the application of the medicine.
Apply a thin layer of Exoderil cream on and around the affected area.
After using Exoderil cream, wash your hands, as otherwise, you may transmit the infection to other areas of your body or to other people.

In order to prevent the recurrence of the disease, treatment should be continued for two weeks after clinical healing.
Symptoms of the disease can start receding after several days. Complete healing of the affected area can take up to 4 weeks.

Keep the affected area clean in order to facilitate healing by occasionally washing the affected area and drying carefully, without rubbing the skin. Even though the treated area can become itchy, try to avoid scratching, as this can cause new damage to the skin or propagate the infection.

If you feel that the effect of Exoderil is too strong or too weak, talk to your doctor or pharmacist.

4. Possible side effects

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

The following incidence categories are used for evaluating side effects:
very common (≥ 1/10);
common (≥ 1/100 to < 1/10);
uncommon (≥ 1/1,010 to < 1/100);
rare (≥ 1/10,000 to < 1/1,000);
very rare (< 1/10,000);
unknown (cannot be estimated from available data)

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Skin and subcutaneous tissue disorders
Unknown: contact dermatitis (skin rash or irritation at the site of application), erythema (reddening of the skin)

General disorders and application site reactions
Unknown: dryness, redness, and burning sensation

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 www.ravimiamet.ee. 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.

Do not store at a temperature higher than 30 °C.

After the initial opening, the cream can be stored for up to 4 weeks at 25 °C.

Do not use this medicine after the expiry date which is stated on the package 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 cream contains
- The active ingredient is naftifine hydrochloride. 1 g of cream contains 10 mg of naftifine hydrochloride.
- The other ingredients are sodium chloride, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate (60), isopropyl myristate and purified water.

What Exoderil cream looks like and contents of the pack
White cream in a metal tube.
The tube contains 30 g of cream.

Marketing Authorisation Holder and manufacturers
Marketing Authorisation Holder:
Sandoz GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

Manufacturers:
Sandoz GmbH
Biochemiestrasse 10
A-6250 Kundl
Austria

Salutas Pharma GmbH
Lange Goehren 3
D-39171 Osterweddingen
Germany

*clarification – 15 g – OTC medicine
30 g – prescription medicine

Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
Sandoz d.d. Estonian branch
Pärnu mnt 105
11312 Tallinn
Phone: 6652400

This leaflet was last revised in June 2021.

*clarification – 15 g – OTC medicine
30 g – prescription medicine