INSTRUCTIONS

NAFTIROX 1% cream

It is applied on the skin.

• ***Active substance:*** Each gram of cream contains 10 mg naftifine hydrochloride.

• ***Excipient(s):*** Benzyl alcohol, PEG-100 stearate, cetyl alcohol, stearyl alcohol, sorbitan stearate, cetyl ester wax, polyethylene glycol 60, isopropyl myristate, sodium hydroxide, pure water.

Before using this drug, read this INSTRUCTIONS FOR USE carefully because it contains important information for you.

• Keep this instruction manual. You might need to read again.

•If you have other questions, please talk your doctor or pharmacist.

• This drug has been prescribed for you personally, do not give it to others.

• When you go to a doctor or hospital while using this drug, tell your doctor that you are using this drug.

*• Follow exactly what is written in this instructions. Do not use **higher or lower** doses of the drug than the recommended dose.*

dose.

The following headings are included in these Instructions for Use.

1.What is NAFTIROX and what is it used for?

2. Things to consider before using NAFTIROX

3.How to use NAFTIROX?

4.What are the possible side effects?

5.Storage of NAFTIROX

1.What is NAFTIROX and what is it used for?

NAFTIROX contains the active ingredient naftifine and is used in the external treatment of fungal infections. NAFTIROX is effective against skin fungi, yeast fungi, mold fungi and other fungi. NAFTIROX is also effective against many different bacteria that frequently occur in fungal infections. The anti-inflammatory effect of NAFTIROX rapidly reduces the symptoms of inflammation and especially itching.

NAFTIROX is a cream available in 30 g tubes.

NAFTIROX is used in the local treatment of the following fungal infections of the skin:

• Fungal infections of the skin or skin folds (seen as redness, scaling and swelling, or itchy blisters)

• Interdigital fungus

• Fungal infections of the nails

• Candida infections of the skin (fungal infection caused by *Candida* species)

• *Pityriasis versicolor* (a common skin disease caused by overgrowth of a fungus on the skin surface)

• Used for the treatment of inflammatory skin fungi (with or without itching)

2. Things to consider before using NAFTIROX

DO NOT USE NAFTIROX in the following situations

If you are hypersensitive to naftifin, benzyl alcohol or other substances contained in the drug.

USE NAFTIROX CAREFULLY in the following situations:

For external use only, avoid contact with eyes.

If the symptoms of your disease do not improve and your drug does not have the expected effect, tell your doctor.

If symptoms persist or the expected success with the application is not achieved, medical consultation should be sought as soon as possible (4 weeks at the latest).

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using NAFTIROX with food and drink

Since it is applied by rubbing on the skin, it is not expected to interact with food and drinks.

Pregnancy

Consult your doctor or pharmacist before using the drug.

If you are pregnant, do not use NAFTIROX unless your doctor recommends it. For safety reasons, the use of NAFTIROX during pregnancy should still be avoided.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this drug.

Do not use NAFTIROX during breastfeeding unless recommended by your doctor. For safety reasons, the use of NAFTIROX should still be avoided during breastfeeding.

Driving and using machines

No effect on the ability to drive and use machines has been observed.

Important information about some excipients contained in NAFTIROX

It may cause regional skin reactions (such as contact dermatitis) due to the stearyl alcohol and cetyl alcohol it contains.

NAFTIROX contains benzyl alcohol, but no warning is required due to the route of administration.

Use with other drugs

There is no information that NAFTIROX interacts with other drugs.

If you are currently using or have recently used any prescripted or non-prescripted drugs, please inform your doctor or pharmacist about them.

3.How to use NAFTIROX?

Instructions for proper use and dosage/frequency of application:

Always use NAFTIROX exactly as your doctor tells you. If you are not sure, consult your doctor or pharmacist.

NAFTIROX is applied to the diseased skin area in a thin layer, preferably before going to bed in the evening, and rubbed lightly. In each application, it should be applied to the entire diseased skin area and 2 cm of the healthy skin outside of it. For fungi between the skin folds, it is useful to place a thin gauze between the folds overnight after applying the medicine.

In nail infections, the nail is cut from the bottom as much as possible. NAFTIROX is applied once a day and rubbed into the nail. It would be appropriate to cover the diseased nail with tape.

For treatment success, NAFTIROX must be administered for a sufficiently long period of time. To prevent recurrence of the disease, application should be continued until at least two weeks after the symptoms disappear.

Pay attention to the following situations in the treatment of fungal infections:

• Clothes should be changed every day, as organisms that cause fungal infections can transfer to your clothes.

• Keep infected skin dry. Avoid wearing tight and airtight clothing (such as synthetic socks inside tight shoes)

• Dry the infected area after washing and change the cloths and towels used every day.

• If you have a fungal infection on your feet, avoid walking barefoot in places such as home, pool or hotel to prevent infecting others and not causing the infection to reoccur.

• Do not go to sauna or steam bath until your fungal infection is completely healed.

Application route and method:

It is applied to the skin or nails.

Before application, the diseased skin or nail area should be washed with lukewarm water and dried thoroughly.

Different age groups:

Pediatric population: The safety and efficacy of naftifine hydrochloride in children and adolescents under 18 years of age have not yet been systematically tested. There is no data.

Use in the elderly:

There is no need for dose adjustment.

Special use cases:

Kidney failure/Liver failure

There is no need for dose adjustment.

If you have the impression that the effect of NAFTIROX is too strong or weak, talk to your doctor or pharmacist.

If you use more NAFTIROX than you should:

There is no need to fear the emergence of life-threatening situations.

If accidentally swallowed, consult a doctor. Appropriate symptomatic treatment is recommended.

If you have used more NAFTIROX than you should, talk to a doctor or pharmacist.

If you forget to use NAFTIROX

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with NAFTIROX is stopped

Be sure to consult your doctor before ending your treatment.

4.What are the possible side effects?

Like all drugs, NAFTIROX may have side effects in people who are sensitive to the substances it contains.

Side effects are classified as shown in the following categories:

Very common: may occur in at least 1 in 10 patients.

Common: It may occur in less than 1 in 10 patients, but in more than 1 in 100 patients.

Uncommon: may occur in less than 1 in 100 patients, but in more than 1 in 1000 patients.

Rare: It can be seen in less than 1 in 1000 patients.

Very rare: It may occur in less than 1 in 10,000 patients.

Unknown: Frequency cannot be estimated based on available data.

If you notice any of the following, tell your doctor:

Unknown (Cannot be estimated with available data):

• Burning, dry feeling on the skin

• Skin redness,

• Contact dermatitis (skin redness or irritation at the application site),

These are mild side effects of NAFTIROX.

Treatment should therefore only be discontinued in some cases. Side effects disappear after stopping treatment.

Reporting side effects:

If you experience any side effects, whether listed in the Instructions or not, talk to your doctor, pharmacist or nurse. Also, report the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on the website www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting any side effects that occur, you will contribute to obtaining more information about the safety of the drug you are using.

If you experience any side effects not mentioned in this instruction manual, inform your doctor or pharmacist.

5. Storage of NAFTIROX

Keep NAFTIROX in its packaging and out of sight and reach of children.

Should be stored at room temperature below 25°C.

If you notice any defects in the product and/or its packaging, do not use NAFTIROX.

Use in accordance with expiration dates.

Do not use NAFTIROX after the expiration date on the packaging.

Do not throw away expired or unused drugs! Give it to the collection system determined by the Ministry of Environment, Urbanization and Climate Change.

Registration owner:

Terra İlaç ve Kimya San. Tic. Inc.

Umraniye/Istanbul

Manufacturing site:

Myfarma İlaç San. ve Tic. A.Ş.

Tuzla / İstanbul

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