EXODERIL CREAM 1%

1. NAME OF THE MEDICINAL PRODUCT
Exoderil Cream 1%

2. QUALITATIVE AND QUANTITAVE COMPOSITION
Each gram of the cream contains Naftifine Hydrochloride 10 mg.
Each gram of the cream contains Benzyl Alcohol 10 mg as a preservative.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Cream.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Exoderil cream is used in adults for the topical treatment of the following skin infections:
- Mycoses of the skin or skin folds (*Tinea corporis, Tinea inguinalis*)
- Interdigital mycoses (*Tinea manuum, Tinea pedis*)
- Mycotic infections of the nails (onychomycoses)
- Candida infections of the skin
- Pityriasis versicolor
- Inflammatory dermatomycoses (with and without pruritus)

The official guidelines and national recommendations on the appropriate use and prescription of antifungal agents are to be considered.

4.2 Posology and method of administration
Posology
EXODERIL cream should be applied once daily to the cleaned and thoroughly dried affected skin and adjacent areas and should be gently massaged.

Paediatric population
The safety and efficacy of naftifine in children and adolescents under 18 years are not yet established. There are no data.

Patients with impaired renal or hepatic function
No dose adjustment is necessary.

Elderly
No dose adjustment is necessary.

Duration of use
Therapy with Exoderil cream is to be continued for at least two weeks after clinical healing in order to avoid relapse.

If no clinical improvement is observed within 4 weeks, the treating physician must be contacted and the therapeutic approach should be reassessed.

Method of use
Naftifine cream is to be applied exclusively to the skin.

Naftifine cream must not come into contact with the eyes or mucous membranes.

Patients should be informed about the usual hygiene measures to prevent sources of infection or reinfection.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
General: Exoderil Cream 1% is for external use only.

If irritation or sensitivity develops with the use of Exoderil Cream 1%, treatment should be discontinued and appropriate therapy instituted.
Exoderil cream should not get in the eyes.

Information for patients:
The patient should be told to:
1. Avoid the use of occlusive dressings or wrappings unless otherwise directed by the physician.
2. Keep Exoderil Cream 1% away from the eyes, nose, mouth and other mucousmembranes.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

4.6 Pregnancy and lactation
Pregnancy and lactation
To date there is no or only very limited experience with the use of naftifine in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
For precautionary reasons, the application of naftifine should be avoided during pregnancy and lactation.

Fertility
No studies have been conducted to investigate the effect of naftifine on fertility.

4.7 Effects on ability to drive and use machines
Naftifine has no influence on the ability to drive and use machines.

4.8 Undesirable effects
The following frequencies are used for the evaluation of side 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	(<1/10,000)
Not known	(cannot be estimated from the available data)

General disorders and administration site conditions
Not known: Sensation of dryness, reddening and burning

Skin and subcutaneous tissue disorders
Not known: Contact dermatitis, erythema

4.9 Overdose
Acute overdose with topical naftifine is unlikely and life-threatening situations are not to be expected. Systemic intoxication with cutaneous application of naftifine is unlikely due to the negligibly small absorption of the active substance through the skin. In case of accidental oral intake an appropriate symptomatic treatment is recommended. No specific antidote is known.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antifungals for dermatological use, antifungals for topical use, other antifungals for topical use.
ATC code: D01AE22
Exoderil cream is intended for external use in case of mycoses and contains naftifine as active substance.

Mechanisms of action
The fungicidal effectivity of naftifine is based on the blockage of the membrane component ergosterol by naftifine which inhibits the enzyme squalene epoxidase. Thereby growth and multiplication of fungal cells are suppressed.

Spectrum of activity
In vitro, naftifine shows a fungicidal effect against the following organisms:
Trichophyton spp.

EXODERIL CREAM 1%

Microsporon spp.
Epidermophyton floccosum

Naftifine has only moderate activity against yeast fungi (*Candida* species), moulds (*Aspergillus* species) and other fungi (e.g. *Sporothrix schenkii*).

In addition to its antimycotic activity, naftifine has also antibacterial activity against various gram-positive and gram-negative germs which often occur together with mycoses.

Furthermore, a substance-own, anti-inflammatory effect appeared within clinical use; this effect leads to rapid reduction of the inflammation signs, particularly also itching.

5.2 Pharmacokinetics properties
About 4% of the cutaneously administered dose is absorbed. Systemic exposure of the organism is therefore very low. Only traces of naftifine are detectable in plasma and urine. Naftifine is almost completely metabolized, resulting in a variety of metabolites that are ineffective against fungi. These are excreted half in the urine and half in the faeces with a half-life of 2 - 4 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium hydroxide
Benzyl alcohol
Sorbitan stearate
Cetyl palmitate
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Isopropyl myristate
Purified water

6.2 Incompatibilities
Not applicable.

Exoderil cream should be applied undiluted and not be mixed with other external preparations, as the efficacy might be worsened due to reduction of the concentration of the active substance.

6.3 Shelf-life
Unopened tube: 3 years.
Shelf-life after first opening: 4 weeks if stored below 25°C.

6.4 Storage condition
Store below 30°C.

6.5 Presentations
White, smooth or slightly granular-smooth, shiny cream in Aluminium tube of 15 g.

7. MANUFACTURER

Salutas Pharma GmbH,
Betriebsstatte Ostwerweddingen,
Lange Goehren 3,
39171 Sulzetal, OT Osterweddingen
Germany

for

Sandoz GmbH
Biochemiestr. 10
A-6250 Kundl, Austria

8. DATE OF REVISION

Feb 2024