EXODERIL CREAM

Naftifine hydrochloride (1% w/w)

What is in this leaflet:

What is Exoderil used for

It is used for the treatment of fungal infections of the skin and skin folds, fungal infections of the feet (especially between the toes and on the sole of the foot), nail and hands.

How Exoderil works

Exoderil is intended for external use only in fungal infections and contains naftifine hydrochloride as its active substance. Exoderil stops the growth and multiplication of fungal cells. It is also active against many different bacteria that often occur together with fungal infections in humans.

Due to its anti-inflammatory action, signs of inflammation rapidly wear off, particularly itching.

Before you use Exoderil

- *When you must not use it*

If you are allergic to naftifine hydrochloride (the active substance), benzyl alcohol (a preservative) or any of the other ingredients of this medicine.

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 using this medicine. For precautionary measures, it should be avoided in pregnancy and breast-feeding.

- *Before you start use it*

Talk to your doctor or pharmacist before using Exoderil if you have any medical conditions.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or intend to take/use any other medicines.

How to use Exoderil

- *How much to use*

Exoderil should be applied once daily and gently rubbed into the cleansed and thoroughly dried affected skin and surrounding area.

Children and adolescents

The safety and efficacy of naftifine in children and adolescents below 18 years of age have not yet been established. No data are available.

People with impaired kidney or liver function

No dose adjustment is necessary.

Elderly

No dose adjustment is necessary.

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

- *How to use it*

Exoderil is to be applied exclusively to the skin.

Exoderil must not come into contact with the eyes, nose, mouth and other mucous membranes.

- *When to use it*

Always use this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

Wash your hands before and after using the cream to prevent sources of infection or reinfection.

- *How long to use it*

Despite a rapid improvement in symptoms (e.g. itching), it is important to continue treatment of fungal skin infections for another two weeks after all signs of disease have disappeared, in order to prevent relapse.

If no improvement in the signs of disease is seen within 4 weeks of the start of treatment, consult your doctor.

If symptoms persist or if treatment is not as successful as expected, you must consult a doctor as soon as possible.

- *If you forget to use it*

It is important to use your medicine every day. However, if you forget to use one or more doses, apply EXODERIL as soon as you remember and then go on as prescribed. Do not use double dose.

- *If you use too much (overdose)*

No life-threatening situations are likely to occur.

If some Exoderil has been swallowed by mistake, consult a doctor.

While you are using it

- *Things you must do*

- Avoid the use of occlusive dressings or wrappings unless otherwise directed by the physician.
- Tell all the doctors, dentists and pharmacists treating you that you are using Exoderil.
- Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

- Do not stop using the medicine unless advised by your doctor.
- Do not use any new medicines without consulting your doctor.
- Do not give Exoderil to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

Exoderil has no influence on the ability to drive or operate machinery.

If irritation or sensitivity develops with the use of Exoderil Cream 1%, treatment should be discontinued.

Side effects

Like all medicines, Exoderil can cause side effects, although not everyone gets them.

In isolated cases, local signs of irritation may occur, such as a sensation of dryness, redness and burning.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers →

Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Exoderil

- *Storage*

Store below 30°C.
After first opening, use within 4 weeks.
Keep out of the reach and sight of children.
Do not use this medicine after the expiry date that is stated on the container or outer carton.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- *What it looks like*

A white, smooth or slightly grainy, shiny cream in an aluminium tube with a plastic closure.

- *Ingredients*
- Active substance

The active substance is naftifine hydrochloride.
1 gram contains 10 mg naftifine hydrochloride.

- Inactive ingredients

Sodium hydroxide
Benzyl alcohol
Sorbitan stearate
Cetyl palmitate
Cetyl alcohol
Stearyl alcohol
Polysorbate 60
Isopropyl myristate
Purified water.

- *MAL Number*

MAL20061492X

Manufacturer

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Product Registration Holder

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