PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed without a doctor's prescription

Daktarin® Cream

Active ingredient -
Each gram contains 20 mg (2%) miconazole nitrate
Inactive and allergenic ingredients: see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
You must use it in the correct manner. Consult the pharmacist if you need further information. Refer to the doctor if signs of the illness (symptoms) worsen or if they do not improve after one month.

1. WHAT IS THE MEDICINE INTENDED FOR?

Daktarin Cream is intended for the treatment of external infections caused by fungi.
What is Daktarin
Daktarin Cream is a medicine which is used for the treatment of fungi and fungi-associated bacterial infections of the skin. Skin infections may appear on the hands, feet, outer ear, trunk or groin, including athlete's foot, jock itch, and intertrigo. The cream contains miconazole nitrate, which works by destroying both the fungi that cause the infection and some of the associated bacteria, which may also be present in the infected areas. The cream also has moisturizing properties to help soothe red and cracked skin.

Therapeutic group:
Skin anti-infective.

2. BEFORE USING THE MEDICINE

The medicine is suitable for most adults and children, but certain people should not use it. If you are in any doubt whatsoever, consult your doctor or pharmacist.

Do not use the medicine if:
You are sensitive (allergic) to the active ingredient, to similar antifungal medicines or to any of the additional ingredients contained in the medicine (see section 6 "Further Information").

Special warnings regarding use of the medicine
- Avoid contact with the eyes.
- Daktarin may cause severe allergic reactions. You must be aware of the signs of an allergic reaction when you use Daktarin Cream (see section 4 "Side effects").

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- Oral anticoagulants (medicines such as warfarin, used to thin the blood).
- If you are unsure about any of the medicines you are taking, show the leaflet or the package to your pharmacist.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, if you think you are pregnant, or are planning a pregnancy, consult with a doctor before using the medicine. Your doctor will decide if you may use this medicine during pregnancy or while breastfeeding.

Important information about some of the ingredients in the medicine
- Benzoic acid (E210) may cause local irritation. It may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Butylated hydroxyanisole (E320) may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

3. HOW SHOULD THE MEDICINE BE USED?

- For dermal use only, namely, the medicine is intended for direct application to the affected skin area.
- Apply to the affected area twice a day. To prevent recurrence of the symptoms, continue the treatment for **seven days** after they have all disappeared. If the symptoms do not disappear and there is no improvement in your condition within 1 month, consult with your doctor.
- Duration of treatment may vary from 2 to 6 weeks, depending on the location and severity of the lesion.
- Check with the doctor or pharmacist if you are uncertain.
- Each tube of cream is sealed – use the cap to pierce the seal.

How to apply the cream
- Wash the affected area and dry it well.
- As many skin lesions are contagious, you should keep a towel and wash cloth for your use only and do not allow anyone else to use them, to avoid contagion.
- Apply the cream to the affected area and surrounding skin. Wash your hands thoroughly after applying the cream (unless the infection being treated is on your hands) to avoid spreading the infection to other parts of the body or to other people. Similarly, clothing which comes into contact with the affected areas, such as socks, should be washed frequently.
- When treating the feet, it is advisable to wear cotton socks, and during the appropriate seasons, it is advisable to wear sandals without socks.

Do not exceed the recommended dose.

If you took an overdose
Exaggerated use may lead to skin irritation, which usually disappears after discontinuation of the treatment.
If someone accidentally swallows Daktarin Cream, refer to a doctor or proceed to a hospital emergency room nearest you, and bring this leaflet and the package with you.

If you forgot to take the medicine
If you forgot to apply a dose, apply the next dose as required. **Do not apply** a double dose.

How can you contribute to the success of the treatment?
- Moisture promotes fungal growth. Therefore, the affected area should be kept dry.
- Wash the affected area before each application of the medicine. Between applications of the cream, an antifungal powder may be applied in order to dry the affected area.
- If the treatment is for your feet, make sure to wash and dry your feet thoroughly, especially between the toes. It is recommended to wear cotton socks. Avoid wearing socks made from wool or synthetic fibers. It is advisable to change them several times a day (depending on the extent of perspiration), and during appropriate seasons, it is recommended to wear sandals without socks.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, Daktarin Cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer immediately for medical treatment if any of the following side effects occur:
Uncommon side effects – Effects occurring in 1–10 users in 1,000:
- Skin burning sensation, local reactions at the treated area (irritation, burning, warmth, itchiness), skin discoloration.
- Skin inflammation, skin hypopigmentation, warmth at the site of application.

Side effects whose frequency is unknown (effects whose frequency has not yet been determined):
- Severe allergic reaction (anaphylaxis) including swelling of the face, lips, mouth, tongue or throat (angioedema), hypersensitivity.
- Allergic reactions such as urticaria, contact dermatitis, skin irritation, rash, redness, itchiness.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Store below 25°C.
The product can be used for up to 3 months after first opening.
Do not discard the medicine into the wastewater or household waste. Consult with the pharmacist how to dispose of the medicine. This will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
PEG-6, PEG-32 and glycol stearate, oleoyl macrogolglycerides, liquid paraffin, benzoic acid (E210), butylated hydroxyanisole (E320), purified water.

What the medicine looks like and the contents of the package:
Daktarin Cream is a white cream.
Daktarin is marketed in tubes containing 15 g or 30 g.
It is possible that not all package sizes are marketed.

Registration holder:
J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer:
Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340, Beerse, Belgium.

Revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
048-83-24118

Daktarin is a registered trademark.