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

The medicine is dispensed with a doctor's prescription only

Name of the medicine, its form and strength

Daktacort® Cream

Active ingredients and concentrations

Miconazole nitrate 20 mg/g (2% w/w); hydrocortisone 10 mg/g (1% w/w)

Inactive and allergenic ingredients in the preparation – see in section 2 "Important information about some of the ingredients of the medicine" and 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.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Daktacort Cream is a cream for the treatment of skin infections caused by fungi, including yeasts. Daktacort Cream is particularly intended for the treatment of infections accompanied by pronounced redness and itching.

Therapeutic group:

Miconazole nitrate – an antifungal from the imidazole group, which works by destroying both the fungi that cause infection and some of the associated bacteria.

Hydrocortisone – a low-potency anti-inflammatory steroid for external use, which reduces inflammation, swelling, redness and itching of the skin.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients or any of the additional ingredients contained in the medicine, or to other similar antifungal medicines. For a list of the additional ingredients, see section 6 "Further Information".
- you have other skin problems, such as cold sores, herpes, chickenpox or shingles. Use this preparation only for the skin problem you have shown to the doctor.

Do not use this preparation if any of these conditions apply to you. If you are uncertain, talk to the doctor or pharmacist before starting to use Daktacort Cream.

Special warnings regarding use of the medicine:

Before beginning treatment with Daktacort, tell the doctor if:

- The affected area is on your face. Do not use Daktacort Cream on the facial area, unless the doctor has instructed you to do so.
- You use rubber (latex) contraceptives: avoid contact between rubber (latex) contraceptives, such as a condom or a diaphragm, and Daktacort Cream. Daktacort Cream can damage the rubber (latex) and reduce its effectiveness. Consult a doctor about using a different type of contraceptive while using this medicine.
- Contact the doctor if you experience blurred vision or other visual disturbances.

Avoid contact with the eyes. If cream gets into the eyes, rinse them thoroughly with water straight away, keeping them open while rinsing.

Children:

Use of the cream is not recommended for a long period on young children (such as every day for several weeks). Do not use on large areas of the child's body or under the diaper unless instructed by the doctor. Once the symptoms of inflammation (redness and irritation) disappear, treatment may be continued with a miconazole cream which only contains the antifungal ingredient (miconazole), instead of Daktacort Cream.

Elderly:

Medicines like Daktacort Cream can cause thinning of the skin when used for a long time without a break. Because thinning of the skin happens naturally in old age, the medicine should be used sparingly for no more than a few weeks in elderly patients. Use only for the time period that the doctor decided.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

Oral blood thinners (anticoagulants) such as warfarin; the doctor may want to check that the anticoagulant is working properly.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, might be pregnant or are planning pregnancy, consult with a doctor before using this medicine.

Driving and operating machinery:

Daktacort Cream should not affect your ability to drive or operate dangerous machinery.

Important information about some of the ingredients of the medicine

- 30 mg benzoic acid in each tube of 15 g cream which is equivalent to 2 mg/g cream.
- Benzoic acid may increase jaundice in newborn babies (up to 4 weeks old).
- Benzoic acid (E210) may cause local irritation.

Butylated hydroxyanisole (E320) may cause a local skin reaction (contact dermatitis) or irritation of the eyes and mucous membranes.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dose is generally application of Daktacort on the skin once or twice a day.

Do not exceed the recommended dosage

For external use only. **Avoid contact with the eyes.**

Opening instructions: Each tube of Daktacort Cream is sealed. Use the cap to pierce the seal of the tube.

How to use:

- Wash the affected skin and dry it well.
- As many skin infections are contagious, you should keep a separate towel for your personal use, in order to avoid infecting others.
- Apply a small amount of Daktacort Cream to the affected skin and gently rub the cream in until it disappears.
- Wash your hands thoroughly after applying the cream, except in cases in which the treatment is intended for the hands, in order to avoid spreading the infection from the affected skin to other parts of the body or to other people. Clothing that comes into direct contact with the infected areas should be washed and changed frequently. If your underwear could come into contact with Daktacort Cream, it is preferable to wear cotton underwear, as Daktacort Cream may damage some synthetic materials.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

If you or your child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

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 the doctor or pharmacist.

4. SIDE EFFECTS

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

Stop using Daktacort and report to the doctor immediately if you notice any of the following signs; you may need medical treatment:

- Swelling of the face, lips, tongue or throat, difficulty swallowing or difficulty breathing.
- Hives, severe irritation or reddening of the skin at the application site or other signs of severe allergy.

The following effects have been reported upon use of Daktacort Cream:

Uncommon side effects – effects that occur in 1-10 in 1,000 users

- Skin irritation
- Burning sensation
- Itchy skin
- Skin sensitivity

Side effects of unknown frequency (effects whose frequency has not been determined):

- Lightening of patches of skin
- Hypersensitivity reaction (such as rash) at the application site, skin inflammation from contact (contact dermatitis). If any of these effects occur, treatment should be stopped.
- Blurred vision

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

Side effects may be reported to the Ministry of Health by clicking 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.
- Keep refrigerated (2-8°C).
- Make sure the tube is always well closed.
- After first opening, use within 3 months when stored in the refrigerator (2-8°C).

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Macrogol 6-32 and Glycol stearate; Peglicol 5 oleate; Liquid paraffin; Benzoic acid; Disodium edetate; Butylated hydroxyanisole; Purified water.

What the medicine looks like and the contents of the package:

The package contains one tube with 15 g of cream. The color of the cream is white.

Importer and Registration Holder and Address: J-C Health Care Ltd., Kibbutz Shefayim, 6099000, Israel.

Revised in March 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 066292361600