DAKTACORT® (miconazole nitrate/hydrocortisone)

Cream and Ointment
For external use only

WHAT IS DAKTACORT® FOR?
DAKTACORT® contains both an antifungal medicine (miconazole nitrate) and a corticosteroid ingredient (hydrocortisone) and is used for treating infection of the skin by fungi including yeasts. DAKTACORT® is particularly recommended when there is pronounced redness and itching.

WHEN NOT TO USE DAKTACORT®
- Do not use DAKTACORT® if you have had a hypersensitivity (allergic) reaction to any component of this product or to other similar antifungal medicines.
- Do not use DAKTACORT® when the skin is infected by viruses (herpes, chickenpox, including chickenpox vaccination) or particular bacteria (tuberculosis of the skin).

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?
Do not apply DAKTACORT® to the eyes.
Wash your hands carefully after you have used DAKTACORT®, except if the treatment is for your hands.
Keep a towel and a flannel (washcloth) for your own use. In this way you avoid infecting other people. Regularly change clothing which comes into contact with the infected skin in order to avoid reinfecting yourself.
Stop treatment with DAKTACORT® if you experience hypersensitivity (allergic) reaction or irritation.
Oral anticoagulants (blood thinning medications): Tell your doctor or pharmacist before use if you are taking an oral blood thinning medication, such as warfarin.
Other medications: The effects and side effects of some other prescription medications can be increased when taken with miconazole. Tell your doctor or pharmacist of any other medications you are taking before using DAKTACORT®.
DAKTACORT® can damage certain synthetic materials. Sometimes underwear is made of such fabrics. If the place where you need to rub in DAKTACORT® comes is contact with your underwear it is preferable to wear cotton underclothing.
Because of its corticosteroid ingredient (hydrocortisone), DAKTACORT® is not recommended for prolonged application. Once the symptoms of inflammation (e.g., redness and itching) have disappeared, treatment may be continued with miconazole cream, which contains only the antifungal
agent (miconazole), instead of DAKTACORT®. Follow the advice of your doctor with regard to length of treatment.

**Children**
In children, DAKTACORT® should be used under the guidance of a health care professional. One should be particularly careful, if DAKTACORT® is applied to large surfaces or under occlusive dressing (including nappies [diapers]), because larger amounts of the drug may be absorbed by the skin. The same holds true for application to the child's face. Because of its corticosteroid ingredient (hydrocortisone), DAKTACORT® is not recommended for prolonged application in children. Once the symptoms of inflammation (e.g., redness and itching) have disappeared, treatment may be continued with miconazole cream, which contains only the antifungal agent miconazole, instead of DAKTACORT®.

**Elderly patients**
Medicines like DAKTACORT® can cause thinning of the skin when used for a long time without a break. Because thinning of the skin happens naturally in older people, this medicine should be used sparingly for no more than a few weeks in elderly patients. Only use it for as long as your doctor tells you.

**Pregnancy and breast-feeding**
Miconazole, an active ingredient of DAKTACORT®, is minimally absorbed into the body when applied on the skin. DAKTACORT® also includes the active ingredient hydrocortisone, a corticosteroid. Hydrocortisone is minimally absorbed into the body when applied on the skin and crosses the placenta where it may affect the developing fetus. If you are pregnant or breast-feeding a baby, ask your doctor if you should use DAKTACORT®.

**Rubber (latex) birth-control devices**
You should avoid contact between rubber (latex) birth-control devices like a condom or a diaphragm (a rubber [latex] cap inserted into the vagina) and DAKTACORT®. The ingredients of DAKTACORT® might damage the rubber (latex), so that pregnancy or sexually transmitted diseases might not be prevented.

**HOW TO USE DAKTACORT® AND HOW MUCH**

Apply DAKTACORT® to the skin **once or twice a day**.

To open the tube unscrew the cap. Then pierce the seal of the tube by means of the pin on the top of the cap.
Wash the infected skin and dry it well. Rub gently into the skin with your finger tips. Do not treat the infected part alone, but apply the product also to the area around it. Wash your hands carefully after applying DAKTACORT®, except if the treatment is for your hands. This is particularly important to avoid transferring the germs of the infected skin to other parts of the body or to other people.

After the symptoms of inflammation have disappeared, you can also continue the treatment with Daktarin cream instead of DAKTACORT®.

Do not stop using DAKTACORT® or miconazole cream until all symptoms have completely disappeared (usually after 2 to 5 weeks).

UNDESIRED EFFECTS

The following unwanted effects have been reported with DAKTACORT®:
Skin irritation or burning sensation at the site where you have applied DAKTACORT® . Hives, itching, and lightening of the skin (hypopigmentation) have also been reported. Irritability may occur in children. Hypersensitivity (allergy) to DAKTACORT® or its ingredients may occur. It can be recognized by localized redness or a rash. If this happens, stop using DAKTACORT® . Very rarely a hypersensitivity (allergic) reaction may lead to shortness of breath and/or a swollen face. If you have trouble breathing, get emergency medical help.
In all cases of suspected allergy you should stop the treatment and consult your doctor or pharmacist.

Do not hesitate to report any undesired effects to your doctor or pharmacist.

OVERDOSE

When DAKTACORT® is applied more frequently or for a longer time than prescribed, it may cause some skin irritation. In this case, stop using the cream and see your doctor.
DAKTACORT® contains a mild corticosteroid. Repeated overdose of corticosteroids may result in such effects as widespread acne and easy bruising. If this is the case, see your doctor. In case you accidentally swallow DAKTACORT® consult your doctor.

HOW TO STORE DAKTACORT®

Always keep the tube properly closed and out of the reach and sight of children.

This medicine can be kept for only a limited period. Do not use DAKTACORT® after the date (month
and year) printed after "EXP", even if it has been stored properly.
You are advised to return old medicines to your pharmacist.

WHAT IS IN DAKTACORT®

DAKTACORT® is a medicine for treating infection of the skin by fungi including yeasts.
The active ingredients in DAKTACORT® are miconazole nitrate and hydrocortisone.

The cream also contains other ingredients, namely benzoic acid, butylated hydroxyanisole, disodium edetate, glycol stearate, liquid paraffin, oleoyl macrogolglycerides, PEG-6, PEG-32, and purified water.

The ointment also contains another ingredient, namely liquid paraffin gel.

Registration holder/Manufacturer:
To be completed by the operating company.

Latest update of this package insert: 27 January 2014
**What you should know about medicines...**

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

*It is important that you use medicines correctly. That is, you should:*
- Always carefully read the full patient information leaflet
- Use medicines only for the purpose for which you were given the medicine;
- Use medicines only in the prescribed amount;
- Use medicines only for the prescribed period of time.

*Keep all medicines out of the reach and sight of children.*

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

*Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example).*

*Make a habit of returning unused or old medicines to your pharmacist.*

*If someone has taken an overdose of a medicine, call a doctor or the poison control centre (tel:....).*