

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Daktacort® 2% / 1% w/w cream

## Miconazole nitrate / hydrocortisone

Daktacort is a registered trademark

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

### What is in this leaflet

- 1 What Daktacort cream is and what it is used for
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## 1 What Daktacort cream is and what it is used for

The name of your medicine is Daktacort 2% / 1% w/w cream. It is called 'Daktacort cream' in this leaflet.

Daktacort cream is a medicine which is used to treat inflamed conditions of the skin such as eczema and dermatitis which may be caused by infection with certain fungi and bacteria.

The cream contains the following ingredients:

- Miconazole nitrate - an antifungal which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present.
- Hydrocortisone - a mild 'topical steroid' which reduces inflammation, swelling, redness and itching of the skin.

## 2 What you need to know before you use Daktacort cream

### Do not use Daktacort cream:

- if you are allergic to miconazole nitrate, hydrocortisone, any of the other ingredients of this medicine (listed in section 6) or to other similar antifungal medicines
- if you have any other skin problems such as cold sores, herpes, chicken pox or shingles. Only use it for the skin problem that you showed the doctor
- if you have tuberculosis or any infections associated with tuberculosis

- Daktacort Cream should not be used on the eyes or face or to treat certain skin infections such as impetigo, cold sores, and acne.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Daktacort cream.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Daktacort cream if:

- The inflamed skin is on your face. You should not use Daktacort cream on your face, unless your doctor has told you to.
- You are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Daktacort cream can damage the latex and stop them from working properly. Talk to your doctor about using another type of contraception while you are using this medicine
- Contact your doctor if you experience blurred vision or other visual disturbances

Keep this medicine away from your eyes. If you get any cream in your eyes, rinse with water straight away. Keep your eyes open when you rinse.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **Children**

- The cream should not be used on young children for long periods of time (such as every day for several weeks)
- The cream should not be used on large areas of a child's body or under a baby's nappy unless your doctor has told you
- The treated skin should not be covered by bandages or other dressings

### **Elderly patients**

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 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.

### **Other medicines and Daktacort cream**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

- Medicines that thin your blood (anticoagulants) such as warfarin. Your doctor may want to check that the anticoagulants are still working properly
- Medicines taken by mouth to treat high blood sugar levels (diabetes)
- A medicine called phenytoin used for epilepsy

### **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.

Do not treat large areas of skin or cover any treated skin with bandages or dressings if you are pregnant or breast feeding.

### **Driving and using machines**

Daktacort cream is not likely to affect you being able to drive or use any tools or machines.

### **Daktacort cream contains benzoic acid (E210) and butylated hydroxyanisole (E320)**

- This medicine contains 60 mg benzoic acid in each tube of 30 g cream which is equivalent to 2 mg/g cream
- Benzoic acid (E210) may cause local irritation
- Benzoic acid 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 eyes and mucosal membranes.

## **3 How to use Daktacort cream**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Daktacort cream is for use on your skin only.

### **How to apply the cream**

- Each tube of Daktacort cream is sealed. Use the cap to pierce the tube
- Wash the infected area and dry it well
- As many skin conditions are infectious, you should keep a towel and flannel for your own use. Do not share them so that you do not infect anyone else
- Apply a small amount of Daktacort cream to the affected area and rub it in gently until the cream has disappeared
- Unless the infected skin is on your hands, wash your hands carefully after applying the cream to avoid spreading the infection to other parts of the body or to other people. Clothing which comes into contact with the infected areas should be washed and changed frequently. If your underwear is likely to come in contact with Daktacort cream, it is preferable to wear cotton underwear, as Daktacort cream may damage some synthetic materials

### **How much to apply - adults and children**

- Unless your doctor tells you differently, apply a small amount of Daktacort cream to the affected area up to 3 times each day
- If your skin problem does not improve in 7 days, tell your doctor

### **If you swallow Daktacort cream**

If anyone accidentally swallows Daktacort cream, contact a doctor or go to your nearest hospital casualty department straight away.

### **If you forget to use Daktacort cream**

- Do not apply the missed dose of cream
- Apply the next dose of cream as usual and keep using the cream as your doctor has told you
- Do not use a double dose to make up for a forgotten dose

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Stop using Daktacort cream and tell your doctor straight away if you notice the following. You may need medical treatment.**

- Swelling of the face, lips, tongue or throat, difficulty swallowing or difficulty breathing
- Hives (also known as nettle rash, or urticarial), severe irritation or reddening of the skin where the cream has been used, or other signs of severe allergy

**Tell your doctor or pharmacist if you notice or suspect any of the following side effects:**

**Uncommon side effects (affects fewer than 1 in 100 people)**

- Burning sensation
- Itchy skin

**Frequency not known:**

- Lighter patches of skin
- Sensitivity reactions (such as rash) at the application site. Inflammation (contact dermatitis). If this occurs stop using the medicine
- Blurred vision

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Daktacort cream

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C to 8°C).

Do not use this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6 Contents of the pack and other information**

### **What Daktacort cream contains**

The active substances are miconazole nitrate (2% w/w) and hydrocortisone (1% w/w).

The other ingredients are macrogol ester, oleoyl macroglycerides, liquid paraffin, benzoic acid (E210), disodium edetate, butylated hydroxyanisole (E320) and purified water.

### **What Daktacort cream looks like and contents of the pack**

Daktacort cream is a white cream available in a 30 g tube.

### **Marketing Authorisation Holder:**

Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL – Co.Cork,  
P43 FA46

### **Manufacturer:**

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Middleton Close, Banbury, OX16 4RS, UK

**For information in large print, tape, CD or Braille, telephone  
1800709122.**

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