

PACKAGE LEAFLET: INFORMATION FOR THE USER

DAKTACORT® CREAM (miconazole nitrate / hydrocortisone)

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
2. What you need to know before you use Daktacort Cream
3. How to use Daktacort Cream
4. Possible side effects
5. How to store Daktacort Cream
6. Contents of the pack and other information

1. What Daktacort Cream is and what it is used for

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
- 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

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

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.

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.

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. In particular, tell your doctor if you are taking;

- Medicines that thin your blood (anticoagulants) such as warfarin. Your doctor may want to check that the anticoagulants are still working properly

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.

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), which can mildly irritate the skin, 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.

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 into 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 2 or 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 of cream to make up for a missed 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.

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, 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)

- Skin irritation
- Burning sensation
- Itchy skin
- Irritability

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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

5. How to store Daktacort Cream

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Store the cream in its original packaging in a refrigerator (2°C to 8°C).
- Do not use Daktacort cream after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- If your doctor decides to stop your treatment, take any leftover cream back to the pharmacy.
- If your cream appears to be discoloured, or shows any other signs of deterioration, take them to your pharmacist who will advise you.
- 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 protect the environment.

6. Contents of the pack and other information

What Daktacort Cream contains

The active substances in Daktacort Cream 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 30g tubes.

Manufacturer

Manufactured by: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium
Or
McGregor Cory Ltd., Middleton Close, Banbury, OX16 8RS, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0536

POM

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000
(Regulatory)

Please be ready to give the following information:
Product name:
DAKTACORT CREAM
Reference No: 21828/0536

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