

PACKAGE LEAFLET: INFORMATION FOR THE USER

Daktacort[®] ointment

Miconazole nitrate and hydrocortisone

Daktacort is a registered trademark

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. What Daktacort ointment is and what it is used for
2. Before you use Daktacort ointment
3. How to use Daktacort ointment
4. Possible side effects
5. How to store Daktacort ointment
6. Further information

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

Daktacort ointment 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 ointment 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. Before you use Daktacort ointment

Do not use Daktacort ointment 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 ointment.

Take special care with Daktacort ointment

Check with your doctor or pharmacist before using this medicine if:

- The inflamed skin is on your face. You should not use Daktacort ointment on your face, unless your doctor has told you to

- The ointment is to be used by children:
 - The ointment should not be used on young children for long periods of time (such as every day for several weeks)
 - The ointment should not be used on large areas of a child's body or under a baby's nappy unless your doctor has told you to
- You are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Daktacort ointment can damage the rubber 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 ointment in your eyes, rinse with water straight away. Keep your eyes open when you rinse.

Elderly patients

Medicines like Daktacort ointment 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.

Taking other medicines

Please tell your doctor if you are taking or have recently taken 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

If you are pregnant or breast-feeding

Ask your doctor for advice before using this medicine if you are pregnant or breast-feeding. Your doctor will decide if you can use Daktacort ointment.

Driving and using machines

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

3. How to use Daktacort ointment

Always use Daktacort ointment exactly as your doctor has told you. Daktacort ointment is for use on your skin only. You should check with your doctor or pharmacist if you are not sure.

How to apply the ointment

- Each tube of Daktacort ointment 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 ointment to the affected area and rub it in gently
- Unless the infected skin is on your hands, wash your hands carefully after applying the ointment 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 ointment it is preferable to wear cotton underwear, as Daktacort ointment may damage some synthetic materials

How much to apply - adults and children

- Unless your doctor tells you differently, apply a small amount of Daktacort ointment 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 ointment

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

If you forget a dose

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

If you have any further questions on the use of this product, 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 ointment and tell your doctor straight away if you notice the following. You may need medical treatment.

- Sudden swelling of the face, lips, tongue, wheezing or shortness of breath
- Severe irritation or reddening of the skin where the ointment 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 (may affect up to 1 in 100 people)

- Skin irritation
- Burning sensation
- Itchy skin
- Hives (also known as nettle rash or urticaria)
- Irritability

Not known (frequency cannot be estimated from the available data):

- 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

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

5. How to store Daktacort ointment

Keep the product out of the reach and sight of children.

Store the ointment in its original packaging. Do not store above 25°C.

Do not use Daktacort ointment after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

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. Further information

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

The other ingredients are liquid paraffin and polyethylene.

What Daktacort ointment looks like and contents of the pack

Daktacort ointment is a white odourless, fatty ointment available in a 30 g tube.

The product licence is held by:

JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Bucks HP12 4EG, UK

Daktacort ointment is made by:

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 0800 7318450.

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