

PACKAGE LEAFLET: INFORMATION FOR THE USER

Daktacort® 2% / 1% w/w ointment

Miconazole nitrate and 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 ointment is and what it is used for
2. What you need to know before you use Daktacort ointment
3. How to use Daktacort ointment
4. Possible side effects
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1. What Daktacort ointment is and what it is used for

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

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. What you need to know 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.

Warnings and Precautions

Talk to your doctor or pharmacist before using this Daktacort ointment if:

- The inflamed skin is on your face. You should not use Daktacort ointment 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 ointment 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 ointment in your eyes, rinse with water straight away. Keep your eyes open when you rinse.

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

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.

Other medicines and Daktacort ointment

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.

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 taking this medicine.

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 this medicine exactly as your doctor has told you. Daktacort ointment is for use on your skin only. 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 to use Daktacort ointment

- 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 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.

Stop using Daktacort ointment 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 urticaria), 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
- 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
- Blurred vision

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 this medicine out of the sight and reach of children.

Store the ointment in its original packaging. Store at or below 25°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 any 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 ointment contains

The active substances 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.

Marketing Authorisation Holder:

Janssen-Cilag Ltd., 50-100 Holmers Farm Way, High Wycombe, Bucks HP12 4EG, UK

Manufacturer:

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

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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