

- This medicine is used to treat inflamed sweat rash and Athlete's Foot skin infections.
- This medicine is for use by adults and children aged 10 years and over.

- **Do not use this medicine:**
  - There are some people who should not use this medicine. *To find out if you are one of them. See Section 2 ►*
  - If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine (listed in section 6) ►

- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in Section 2 ►
  - If you are taking any **other medicines**. See Section 2 ►

- **Follow the instructions on how to use this product carefully.** See Section 3 ►

**Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

## 1 What the medicine is for

Daktacort Hydrocortisone Cream is a medicine which is used to treat inflamed sweat rash or Athlete's Foot.

The cream contains the following ingredients:

Hydrocortisone acetate is a mild 'topical steroid' which reduces inflammation, swelling, redness and itching of the skin.

Miconazole nitrate is an antifungal which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present.

Sweat rash (candida intertrigo, or 'thrush' of the skin folds) is a sore, itchy red rash found in areas where the skin rubs together e.g. below or between the breasts, underarms, tops of legs or the groin or other skin areas.

Athlete's Foot is a fungal skin infection causing soreness, itching and flaking between the toes or on the soles or sides of the feet.

If you have a fungal infection without any symptoms of inflammation, an antifungal medication without hydrocortisone acetate may be more appropriate.

Ask your doctor or pharmacist if you are in doubt.

This medicine is for use in adults and children aged 10 years and over.

## 2 Before using this medicine

This medicine is suitable for most adults and children but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### **X Do not use this medicine...**

- If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine (listed in section 6)
- If you have any other **skin problems such as cold sores, acne, herpes, chicken pox, or shingles.**
- If your skin is broken.
- On large areas of your body, under dressings, or baby's nappies.
- For more than 7 days.
- On your face, eyes or mucous membranes.
- On the anal or genital area, unless your doctor has told you to.
- If it is for a child under 10 years of age, unless your doctor has told you to.
- To treat **ringworm**, unless your doctor has told you to.
- To treat **any other infections which occur as a result of your original infection**, unless your doctor has told you to.

If this applies to you, **get advice from a doctor or pharmacist without using Daktacort Hydrocortisone Cream.**

### **A Elderly patients**

Medicines like Daktacort Hydrocortisone 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 up to 7 days.

### **A Talk to your doctor or pharmacist if you are taking...**

- *Oral anticoagulants* (drugs used to **thin the blood**, such as warfarin).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

### **A If you are pregnant or breast-feeding**

- Ask your doctor or pharmacist for advice before using this medicine if you are pregnant or breast-feeding.

### **A Special warnings about this medicine**

- Avoid contact with the eyes. If contact occurs rinse with water straight away.
- Daktacort can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking Daktacort. See 'Possible side-effects'
- Do not use for more than 7 days.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- If you are using a 'barrier' method of contraception (condoms or diaphragms) you should avoid contact with the cream, as the ingredients might damage the rubber so that pregnancy or sexually transmitted diseases might not be prevented.

### **A Some of the ingredients can cause problems**

- This medicine contains 2 mg of benzoic acid (E210) in each gram and may cause local irritation.
- Butylated hydroxyanisole (E320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## 3 How to use this medicine

**Check the table that follows to see how much medicine to use.**

- For topical use only, which means it is applied directly to the affected area of skin.
- Do not use more than the stated dose shown in the table.

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

- Wash the infected area and dry it well. As many skin conditions are contagious, you should keep a towel and flannel for your own use and not share it so that you do not infect anyone else.
- Apply the cream onto the infected area and surrounding skin.
- 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. Similarly, clothing which comes into contact with the infected areas, such as socks, should be washed and changed frequently.

It is preferable to wear cotton underwear if it is likely to come into contact with the cream, as the cream may damage some synthetic materials.

### **i Adults and children aged 10 years and over**

| Age  | Dose   |
|--|--|
| <b>Adults and children aged 10 years and over</b>  | Put a small amount of the cream on the affected area <b>twice</b> daily. Rub it in gently until the cream has disappeared. |
| <ul style="list-style-type: none"> <li>■ Do not use for more than 7 days.</li> <li>■ If symptoms persist talk to your doctor.</li> </ul> |  |

### **A If anyone has swallowed this product**

If anyone accidentally swallows Daktacort Hydrocortisone Cream, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you.

### **A If you forget to use the medicine**

If you forget to use a dose, use the next dose when needed. **Do not** use a double dose.

## 4 Possible side-effects

Daktacort Hydrocortisone Cream can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

**If you experience any of the following, stop using the medicine and seek immediate medical help:**

### **Frequency not known:**

- Severe allergic reactions including swelling of the face, lips, tongue or throat.
- Light headedness, generalised itch, wheezing or difficulty in breathing.

**If you experience any of the following, stop using the medicine and talk to your doctor:**

**Uncommon** (affects fewer than 1 in 100 people):

- Skin irritation, burning sensation, itchy skin, hives (also known as nettle rash or urticaria).

### **Frequency not known:**

- Blurred vision, sensitivity reactions at the site of application, skin rash, redness, inflammation or lighter patches of skin.

**Other effects which occur are listed below:**

**Uncommon:**

- Irritability in children.

### **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](http://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 Storing this medicine

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

Do not use this medicine after the expiry date which is stated on the label and carton after 'Expiry'. 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 Further information

### What's in this medicine?

#### The active ingredients in 1 g of Daktacort

**Hydrocortisone Cream are:** Miconazole nitrate 20 mg and Hydrocortisone acetate equivalent to 10 mg of hydrocortisone.

**Other ingredients are:** Macrogol 6-32 stearate, glycol stearate, oleoyl macrogolglycerides, liquid paraffin, butylhydroxyanisole, benzoic acid, disodium edetate, sodium hydroxide and purified water.

### What the medicine looks like

Daktacort Hydrocortisone Cream is a white cream available in a 15 g tube.

#### Product Licence holder:

McNeil Products Limited, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

#### Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340, Beerse, Belgium.

#### This leaflet was revised October 2020.

Daktacort is a registered trade mark.

## 7 Facts about Athlete's Foot:

### How do you catch Athlete's Foot?

It's extremely infectious so anyone can pick it up, especially people sharing communal changing rooms and showers.

Once the fungal spores have been transferred onto the feet, they thrive in the warm, moist areas between the toes. The skin soon becomes inflamed and itchy with flaking or cracking occurring.

The infected flakes of skin are then shed onto the floor or into the socks and shoes by walking or friction.

Someone else will be easily infected if they step on these flakes, or if they share towels or footwear with someone who has already got Athlete's Foot.

What is more, even if you've already got rid of your Athlete's Foot, it's very easy to re-infect yourself. The spores can live on or in your shoes or socks and if you don't change them regularly, or treat them with antifungal powders or spray powders, the Athlete's Foot soon returns.

### How to prevent re-infection

If you want to avoid the vicious circle of re-infection, here are a few helpful hints.

- Spray inside your shoes and socks with fungicidal powder before putting them on.
- Don't wear the same pair of shoes every day. This helps reduce the build-up of sweat which provides the moisture on which the fungus thrives.
- Avoid synthetic footwear. Choose cotton socks and leather shoes which allow your feet to breathe.
- Avoid sharing towels or footwear.
- Avoid walking barefoot in changing rooms.
- Dry thoroughly between your toes and keep toenails short as this reduces the number of places fungi can grow.