

DAKTARIN[®] CREAM/TINCTURE

Miconazole (20mg)

What is in this leaflet

1. What DAKTARIN[®] is used for
2. How DAKTARIN[®] works
3. Before you use DAKTARIN[®]
4. How to use DAKTARIN[®]
5. While you are using it
6. Side effects
7. Storage and disposal of DAKTARIN[®]
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

What DAKTARIN[®] is used for

DAKTARIN[®] is used for treating infection of the skin by fungi including yeasts.

DAKTARIN[®] Cream is used for:

- Infections on the scalp, the beard, the trunk, the feet and hands and in the groin;
- Diaper rash in babies.

DAKTARIN[®] Tincture can only be used for:

- nail infections.

How DAKTARIN[®] works

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.

Before you use DAKTARIN[®]

- When you must not use it

Do not use DAKTARIN[®] if you know you are hypersensitive to it or to other similar antifungal medicines.

Pregnancy and lactation

Pregnancy

DAKTARIN[®] is minimally absorbed into the skin/nail. If you are pregnant or planning to become pregnant, ask your doctor if you should use DAKTARIN[®].

Breastfeeding

It is not known whether the active ingredient is excreted in human breast milk. If you are nursing, ask your doctor if you should use DAKTARIN[®].

- Before you start use it

Oral anticoagulants (blood thinning medications): Ask your doctor or

pharmacist before use if you are taking an oral blood thinning medication, such as warfarin.

- Taking other medicines

Other medications: The effects and side effects of some other prescription medications, when taken with miconazole, can be increased. Ask your doctor or pharmacist before use if you are taking any other medications.

How to use DAKTARIN[®]

DAKTARIN[®] Cream:

For a successful treatment, apply DAKTARIN[®] Cream every day.

- Apply DAKTARIN[®] Cream to the skin twice a day.
- To open the tube, unscrew the cap. Then pierce the seal of the tube using the pin on the top of the cap.

Wash the infected skin and dry it well. Rub DAKTARIN[®] Cream gently into the skin with your fingertips. Do not treat the infected skin alone. Apply the product to the area around it also.

Wash your hands carefully after applying the cream. This is particularly important to avoid transferring the germs of the infected skin to other parts of the body or to other people.

DAKTARIN[®] Tincture:

For a successful treatment, apply DAKTARIN[®] Tincture every day.

DAKTARIN[®] Tincture is applied with a brush which is attached to the cap of the bottle.

Cut the infected nail as short as possible. Once to twice a day, apply some tincture to the nail, the area around it and, if possible, under it. Allow to dry. After the tincture has dried, an occlusive film remains.

Before applying the tincture again, you should clean the nail with a swab saturated with acetone (sometimes also to remove nail polish). If this is not done, the layers will become too thick and the medicine in DAKTARIN[®] Tincture cannot reach the nail any more.

- How much to use

If you are using **DAKTARIN[®] Cream**: apply twice a day.

If you are using **DAKTARIN[®] Tincture**: apply once or twice a day.

- When to use it

Always take this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

DAKTARIN[®] Cream: Do not stop using the medicine until at least a week after all symptoms have disappeared. Depending on the type and extent of the infection, the treatment may last 2 to 6 weeks.

DAKTARIN[®] Tincture: You should continue the treatment until a new nail starts growing. Stop using DAKTARIN[®] Tincture only after you have seen that this nail is completely normal. That will take at least 3 months.

Follow the advice of your doctor with regard to length of treatment. Please ask your doctor or pharmacist if you are not sure.

- If you forget to use it

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

- If you use too much (overdose)

When DAKTARIN[®] is applied more frequently than prescribed; it may cause some redness, swelling or a burning sensation. In this case, it is sufficient to skip one or two applications and start again according to the normal scheme.

Accidental swallowing of a small amount of DAKTARIN[®] Cream is normally harmless.

Accidental swallowing of DAKTARIN® Tincture may cause stomach irritation.

If this occurs, seek medical attention immediately. Call your doctor to make sure that there are no problems

While you are using it

- Things you must do

DAKTARIN® Cream:

Wash your hands carefully after you have used DAKTARIN® except if the treatment is for your hands.

DAKTARIN® Cream and Tincture:

Keep a towel and a washcloth for your own use. In this way you avoid infecting other people. Regularly change clothing which comes into contact with the infected skin in order to avoid reinfecting yourself.

- Things you must not do

DAKTARIN® Cream:

Do not apply DAKTARIN® Cream to the eyes.

DAKTARIN® Tincture:

Do not bring DAKTARIN® Tincture into contact with open wounds, the eyes, or mucous membranes.

- Things to be careful of

DAKTARIN® can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking DAKTARIN®. See "Side effects".

Driving and using machines

DAKTARIN® is not likely to affect you being able to drive or use any tools or machines.

Side effects

Like all medicines, DAKTARIN® can cause side effects, although not everybody gets them. DAKTARIN® is usually well tolerated.

- Burning sensation of the skin
- Skin inflammation
- Light skin patches
- Problem where DAKTARIN® has been applied on the skin

- Burning feeling where DAKTARIN® has been on the skin
- Itching where DAKTARIN® has been on the skin
- Warm feeling where DAKTARIN® has been on the skin
- Redness of the skin
- Itching
- Allergic skin rash caused by contact with something on the skin
- Skin rash
- Hives

Do not hesitate to report any other side effects to your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting side effects to medicines (ConSERF) or vaccines (AEFI).

Storage and disposal of DAKTARIN®

- Storage

Always keep the medicine properly closed.

Keep out of the reach and sight of children.

This medicine can be kept for only a limited period. Do not use DAKTARIN® after the date (month and year) printed after "EXP", even if it has been stored properly.

DAKTARIN® Cream:

Do not store above 25°C.

DAKTARIN® Tincture:

Do not store above 30°C.

- Disposal

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 to protect the environment.

Product description

- What it looks like

DAKTARIN® Cream: White, homogenous, odourless cream filled per 15g in aluminium tubes.

DAKTARIN® Tincture: Clear colourless solution comes in bottle of 30 milliliters with a brush attached to the cap

- Ingredients

- Active ingredient

DAKTARIN® Cream: Each gram contains 20 mg miconazole.

DAKTARIN® Tincture: Each milliliter contains 20 mg miconazole.

- Inactive ingredients

DAKTARIN® Cream: benzoic acid, butylated hydroxyanisole, liquid paraffin, oleoyl macroglycerides, PEG-6 (and) PEG-32 (and) glycol stearate, and water.

DAKTARIN® Tincture:

acrylic/acrylate copolymers 750mPa.s & 5mPa.s, alcohol, and propylene glycol.

- MAL numbers:

DAKTARIN® Cream:

MAL19900260AZ

DAKTARIN® Tincture:

MAL19990597ACZ

Manufacturer

DAKTARIN® Cream:

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

DAKTARIN® Tincture:

Lusomedicamenta Sociedade Technica Farmaceutica S.A, Estrada Consiglieri Pedroso, 69B, Queluz De Baixo, 2730-055 Barcarena, Portugal.

Product registration holder

JNTL (Malaysia) Sdn. Bhd.

Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya Selangor, Malaysia.

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