

MICONAZOLE**MEDONAZOLE**

20 mg/g (2% w/w) Topical Cream
ANTIFUNGAL

NAME OF THE PRODUCT:

Miconazole (MEDIZOLE)

DESCRIPTION OF THE PRODUCT:

White soft cream

STRENGTH OF THE MEDICINE:

2% w/w Topical Cream

WHAT IS IN THE MEDICINE?

Each gram contains:

Miconazole Nitrate BP 20 mg (2% w/w)

WHAT IS THIS MEDICINE USED FOR?

Used in the treatment of fungal and associated bacterial infections of the skin. Skin infections may appear on the hands, feet, outer ear, trunk or groin and include athlete's foot, dhotie itch and intertrigo. Miconazole Cream is also effective against infected nappy rash. The cream contains miconazole nitrate which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present. It also has moisturising properties to help soothe cracked, red skin.

This medicine is for use in adults and children of all ages.

HOW MUCH & HOW OFTEN SHOULD YOU USE THIS MEDICINE?

- To be applied directly to the affected area of skin.
- 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.
- 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.

Adults and children of all ages	
Age	Dose
Adults and children of all ages	Skin infections: Apply the cream to the infected skin twice a day.

- Continue treatment until the lesions have completely healed.
- If symptoms persist talk to your doctor.
- If the powder is used with the cream, a once daily application of both formulations is recommended. The duration of therapy varies from 2 to 6 weeks depending on the localization and severity of the lesion. Treatment should continue for at least one week after the disappearance of all signs and symptoms.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE:

Do not use Miconazole Cream

- If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine.

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

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE:

- Avoid contact with the eyes.
- If you experience any irritation or sensitivity to the cream, stop using this medicine.
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it

UNDESIRABLE EFFECTS OF THIS MEDICINE:

Miconazole Cream can have side-effects, like all medicines, although these may not affect everyone.

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

Very rare: may affect up to 1 in 10,000 people

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

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

Very rare: may affect up to 1 in 10,000 people.

- Allergic reactions such as skin rash, itchiness, hives, swelling, redness or a burning feeling.
- Hypersensitivity reactions (such as rash) at the application site. If this occurs stop using the medicine.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

- Talk to your doctor or pharmacist if you are taking oral anticoagulants (drugs used to thin the blood such as warfarin).
- The effects and side-effects of some drugs may increase when co-administered with miconazole. These include:
- tablets taken to control blood sugar such as sulphonylureas including gliclazide and glibenclamide.

- phenytoin which is used to control epilepsy. If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

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

SIGNS AND SYMPTOMS OF OVERDOSE:

Prolonged and excessive use can result in skin irritation, which usually disappears after discontinuation of therapy. Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Seek medical attention immediately.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperature not exceeding 30°C. Keep product away from children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

If any undesirable effect occurs.

Name and address of marketing authorization holder:

MEDINOVA PHARMACEUTICAL INC.
3270-C Armstrong Rd., Merville, Brgy. 201, Pasay City,
Metro Manila, Philippines

Name and address of manufacturer:

S KANT HEALTHCARE LTD.
Plot 1802-1805, G.I.D.C. Phase III,
Vapi, Gujarat, 396 195 India

ADR Reporting Statement:

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

FDA Reg. No. DRP-13113

Date of first authorization:

Date of revision of patient information leaflet:

Reference:

Miconazole 2% Cream (DAKTARIN)

<https://www.hpra.ie/img/uploaded/swedocuments/49f2c75b-8d86-4680-9617-c3e436b110b6.pdf>