

# MICONAZOLE NITRATE

## FUNGIGEN

20 mg (2% w/w) per g Cream

Antifungal for Topical Use

(Imidazole and Triazole Derivatives)

### What is in the Medicine?

Fungigen contains Miconazole Nitrate, a medicine that belongs to the group of "Antifungals". Miconazole 2% cream is used for infections of the skin or nails caused by fungi including yeasts, and some bacteria. Infections may appear on the: trunk, hands or feet, scalp or outer ear, and groin.

Miconazole cream works by destroying the fungus and associated bacteria which may be present.

### Strength of the Medicine

Each gram contains 20 mg(g) (2% w/w) of Miconazole Nitrate BP

### What is this Medicine used for?

For the treatment of mycotic infestations of the skin and nails. Miconazole 2% Cream is indicated for topical application in the treatment of fungal infections of the skin. Skin infections due to dermatophytes or yeasts and other fungi e.g., *Tinea capitis*, *Tinea corporis*, *Tinea manuum*, *Tinea barbae*, *Tinea cruris*, *Tinea pedis* (athlete's foot). Used in mycoses secondarily infected with such bacteria (e.g., in napkin dermatitis) since miconazole nitrate has an antibacterial effect on gram-positive bacteria.

Just apply a small amount on the affected area(s) and massage the cream with fingers until Miconazole cream is evenly distributed on the skin.

### How much and how often should you use this Medicine?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### How often you should use Miconazole cream

Apply some cream to the lesions twice daily. Rub the cream into the skin with finger until it has fully penetrated the skin.

If the powder is used with the cream, a once daily application of both formulation is recommended.

The duration of therapy varies from 2-6 weeks depending on the localization and the severity of the lesion.

Treatment should be continued at least 1 week after disappearance of all signs and symptoms.

For skin infections

• Use the cream twice a day - once in the morning and again at night. Keep using the cream for at least 7 days after all signs of infection have gone away. This will stop the infection from coming back. - 3

For nail infections

• Use the cream once or twice a day. Your doctor will tell you which one. Keep using the cream for 10 days after all signs of infection have gone away. This will stop the infection from coming back.

### When should you not use this medicine?

Do not use Miconazole cream if you are allergic to miconazole, any of the other ingredients of this medicine or to other similar antifungal medicines Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using miconazole cream.

### Care that should be taken when taking this Medicine?

- Each tube of Miconazole cream is sealed. You will need to use the cap to pierce the seal
- Rub the cream gently into the affected area and surrounding skin with clean fingers
- Do not put Daktrin cream into or near the eyes - it is for use on the skin and nails only
- Do not swallow the cream

Personal hygiene

• Unless the affected skin is on your hands, wash your hands with soap and water after using the cream

• Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people

• Do not allow other people to use your flannel or towel. This will stop them from getting your infection

• Clothing that touches infected skin should be washed and changed often. Daktrin cream is non-greasy and should not stain clothes

### Undesirable Effects of this Medicine

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Miconazole cream and tell your doctor straight away if you notice the following. You may need medical treatment.

Very rare (affects less than 1 in 10,000 people)

- Swelling of the face, tongue or throat, difficulty swallowing or difficulty breathing,
- Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction.

Tell your doctor or pharmacist if you notice any of the following side effects:

Very rare (affects less than 1 in 10,000 people)

- Burning sensation, itching, redness, or rash on the skin.

Rare (affects less than 1 in 1,000 people)

- Local irritation of the treated area. This is much milder than an allergic reaction.

### 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?

- Do not apply the forgotten dose of cream.

• Apply the next dose of cream as usual and keep using the cream as your doctor has told you.

• Do not use a double dose of cream to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### Signs and Symptoms of Overdose

Excessive use can result to skin irritation: redness, swelling, and burning sensation.

### What to do when you have taken more than the recommended dosage?

In this case, it is sufficient to skip one or two applications and start again according to the normal scheme.

#### Accidental Ingestion

Miconazole cream is intended for topical use, not for oral use. Should accidental oral ingestion of large quantities of Miconazole cream occurs, use appropriate supportive care.

### How should you keep this Medicine?

Store at temperatures not exceeding 30°C. Keep out of reach of children.

### When should you consult your doctor?

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this Patient Information Leaflet.

For suspected adverse drug reaction, report to the FDA: [www.fda.gov/ph](http://www.fda.gov/ph).

Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

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