

MICONAZOLE (Topical)

Category

Antifungal (topical).

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Candidiasis, cutaneous (treatment) Miconazole is indicated in the topical treatment of cutaneous candidiasis caused by *Candida albicans*. 8

Tinea corporis (treatment)

Tinea cruris (treatment) or

Tinea pedis (treatment) Miconazole is indicated in the topical treatment of tinea corporis (ringworm of the body), tinea cruris (ringworm of the groin; jock itch), and tinea pedis (ringworm of the foot; athlete's foot) caused by *Trichophyton rubrum*, *T. mentagrophytes*, and *Epidermophyton floccosum*. 8

Tinea versicolor (treatment) Miconazole is indicated in the topical treatment of tinea versicolor (pityriasis versicolor; "sun fungus") caused by *Malassezia furfur* (*Pityrosporon orbiculare*). 8

[Paronychia (treatment)] 1

[Tinea barbae (treatment)] or 1

[Tinea capitis (treatment)] Miconazole is used in the topical treatment of paronychia, tinea barbae, and tinea capitis. 1

Not all species or strains of a particular organism may be susceptible to miconazole.

Pharmacology

Mechanism of action/Effect:

Fungistatic; may be fungicidal, depending on concentration; inhibits biosynthesis of ergosterol or other sterols, damaging the fungal cell wall membrane and altering its permeability; as a result, loss of essential intracellular elements may occur; also inhibits biosynthesis of triglycerides and phospholipids by fungi; in addition, inhibits oxidative and peroxidative enzyme activity, resulting in intracellular buildup of toxic concentrations of hydrogen peroxide, which may contribute to deterioration of subcellular organelles and cellular necrosis. In *Candida albicans*, inhibits transformation of blastospores into invasive mycelial form. 18

Precautions to Consider

Pregnancy/Reproduction

Problems in humans have not been documented.

Breast-feeding

Problems in humans have not been documented.

Pediatrics

Appropriate studies on the relationship of age to the effects of topical miconazole have not been performed in the pediatric population. However, no pediatrics-specific problems have been documented to date.

Geriatrics

Appropriate studies on the relationship of age to the effects of topical miconazole have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¼ not necessarily inclusive (>> = major clinical significance).

Risk-benefit should be considered when the following medical problem exists

Sensitivity to topical miconazole

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¼not necessarily inclusive:

Those indicating need for medical attention 8

Blistering, burning, redness, skin rash, or other sign of skin irritation not present before therapy

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Miconazole (Topical).

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Sensitivity to topical miconazole
Proper use of this medication

>> Avoiding contact with the eyes

Applying sufficient medication to cover affected area, and rubbing in gently

Proper administration technique for topical aerosol powder, topical powder, and topical aerosol solution

>> Not applying occlusive dressing over this medication unless directed to do so by physician

>> Compliance with full course of therapy

>> Proper dosing

Missed dose: Applying as soon as possible; not applying if almost time for next dose

>> Proper storage

Precautions while using this medication

Checking with physician or pharmacist if no improvement within 4 weeks

Side/adverse effects

Signs of potential side effects, especially blistering, burning, redness, skin rash, or other sign of skin irritation not present before therapy

General Dosing Information

Use of topical antifungals may lead to skin sensitization, resulting in hypersensitivity reactions with subsequent topical or systemic use of the medication.

The lotion is preferred for use on intertriginous areas; if the cream is used, it should be used sparingly and massaged in well to avoid maceration effects. 8

When this medication is used in the treatment of candidiasis, occlusive dressings should be avoided since they provide conditions that favor growth of yeast and release of its irritating endotoxin.

To reduce the possibility of recurrence, Candida infections, tinea cruris, and tinea corporis should be treated for 2 weeks and tinea pedis for 1 month. 8

Topical Dosage Forms

MICONAZOLE NITRATE TOPICAL AEROSOL POWDER

Usual adult and adolescent dose

Tinea corporis or

Tinea cruris or

Tinea pedis^{3/4}

Topical, to the skin, two times a day, morning and evening. 12

Usual pediatric dose

See Usual adult and adolescent dose.

Strength(s) usually available

U.S. 2% (OTC)[Micatin (alcohol 10%)] 12, 24

Canada Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer.

Auxiliary labeling:

- Shake well.
- For external use only.
- Continue medication for full time of treatment.
- Store away from heat and direct sunlight.

MICONAZOLE NITRATE TOPICAL AEROSOL SOLUTION

Usual adult and adolescent dose

See Miconazole Nitrate Topical Aerosol Powder. 12

Usual pediatric dose

See Miconazole Nitrate Topical Aerosol Powder.

Strength(s) usually available

U.S. 2% (OTC)[Micatin (alcohol 17%)] 11, 24

Canada Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from freezing.

Auxiliary labeling:

- Shake well.
- For external use only.

- Continue medication for full time of treatment.
- Store away from heat and direct sunlight.

MICONAZOLE NITRATE CREAM USP

Usual adult and adolescent dose

Candidiasis, cutaneous or
Tinea corporis or
Tinea cruris or
Tinea pedis^{3/4}
Topical, to the skin, two times a day, morning and evening.
Tinea versicolor ⁸/₄
Topical, to the skin, once a day.

Usual pediatric dose

See Usual adult and adolescent dose.

Strength(s) usually available

U.S.^{3/4}/₂% (Rx/OTC)[Micatin] [Monistat-Derm] [Generic] 8, 19, 22, 23, 24

Canada^{3/4}/₂% (Rx)[Micatin] [Monistat-Derm] 9, 10, 21

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a collapsible tube or tight container. Protect from freezing.

Auxiliary labeling:

- For external use only.
- Continue medication for full time of treatment.

MICONAZOLE NITRATE LOTION

Usual adult and adolescent dose

See Miconazole Nitrate Cream USP.

Usual pediatric dose

See Miconazole Nitrate Cream USP.

Strength(s) usually available

U.S.^{3/4}/₂% (Rx)[Monistat-Derm] 8

Canada 2% (Rx)[Micatin] 10

Packaging and storage:

Store between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from freezing.

Auxiliary labeling:

- Shake well.
- For external use only.
- Continue medication for full time of treatment.

MICONAZOLE NITRATE TOPICAL POWDER USP

Usual adult and adolescent dose

Tinea corporis or

Tinea cruris or

Tinea pedis

See Miconazole Nitrate Topical Aerosol Powder. 12

Usual pediatric dose

See Miconazole Nitrate Topical Aerosol Powder.

Strength(s) usually available

U.S. 2% (OTC)[Micatin] [Zeasorb-AF] 20, 24

Canada Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer.

Auxiliary labeling:

- For external use only.
- Continue medication for full time of treatment.
- Keep container tightly closed.
- Keep in a dry place.