

MICONAZOLE NITRATE- miconazole nitrate solution

AvPAK

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Miconazole Nitrate 2% Solution

Topical Antifungal

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Inactive Ingredients

Glacial Acetic Acid, Laureth-4, Propylene glycol, Sodium Hydroxide, Sodium Metabisulfite

Purpose

Topical Antifungal

Uses

Cures most athlete's foot (tinea pedis) and ring worm (tinea corporis). Under professional supervision, Miconazole Nitrate 2% Solution can be used for the treatment of superficial skin infections caused by yeast (Candida albicans).

WARNINGS

DO NOT USE ON CHILDREN UNDER TWO YEARS OF AGE EXCEPT UNDER THE ADVICE AND SUPERVISION OF A DOCTOR. FOR EXTERNAL USE ONLY. KEEP OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact Poison Control Center immediately. Avoid contact with eyes. If irritation occurs or if there is no improvement within four weeks, discontinue use and consult a doctor or pharmacist. Do not use if you are diabetic or have circulatory, renal, or hepatic problems, consult a doctor or pharmacist before using.

Directions

Cleanse and dry affected areas. Apply a thin application twice a day (morning and night) on skin under nails and surrounding cuticle areas or as recommended by your doctor or pharmacist. Remove Miconazole

Nitrate 2% Solution from any untreated areas.

Remove from all inanimate environmental surfaces. Supervise children in the use of this product. For athlete's foot, pay special attention to the spaces between the toes; wear well fitting, ventilated shoes and change shoes and socks at least once a day. For athlete's foot and ringworm use daily for 4 weeks. For fungal infections of the nail bed, if conditions persist, consult a doctor who may choose to debride or remove the nail to allow application of Miconazole Nitrate 2% Solution to the skin of the nail bed. This product is not effective on the scalp or nails.

Other Information

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. [See USP Controlled Room Temperature]. Protect from freezing. If freezing occurs, warm to room temperature.

For product questions, or to report a serious adverse event, call 1-855-361-3993.

Regardless of your level of personal hygiene, your skin can be covered with microscopic organisms, including molds and yeast like fungi. While most microorganisms are not harmful, some can invade your skin and cause an infection.

FUNGUS TYPES:

Mold-like fungi called dermatophytes cause athlete's foot, jock itch, and ringworm of the skin or scalp. These fungi live on dead tissue of your hair, nails, and the outer layer of your skin. Poor hygiene, continually moist skin, and minor skin or nail injuries increase your chances of developing a fungal infection.

Athlete's Foot and Jock Itch: Athlete's foot and jock itch are skin conditions caused by fungi that thrive in warm, moist areas. In all cases, itching and rash are the most noticeable symptoms. Athlete's foot produces itching, stinging, and burning on the soles of the feet, palms and between fingers and toes. Cracking and peeling of the skin may occur as well. Jock itch consists of itching in the groin and anal areas.

Ringworm: Most common in children, ringworm causes a ringshaped pattern on the skin or scalp that grow outward as the infection spreads. The ring itself is the most actively infected area, while the skin inside the ring is less actively infected. Ringworm is very contagious and can be passed from shared hats, combs or brushes and barber tools. Ringworm infections can also develop from contact with pets or domestic animals. To treat the infection, wash the area and dry thoroughly. Apply a thin layer of Miconazole Nitrate 2% Solution twice a day (morning and evening) over the affected area or as recommended by a doctor. Use daily for 4 weeks.

PREVENTIONS AND TREATMENT:

Athlete's Foot and Jock Itch: Good personal hygiene is essential in preventing or treating athlete's foot and jock itch. To prevent athlete's foot, wear well-fitting, well-ventilated shoes and change shoes and socks at least once a day. For treatment, apply Miconazole Nitrate 2% Solution twice daily (morning and evening) or as directed by a doctor and pay special attention to the areas between toes. Apply twice a day on skin under nails and

surrounding cuticle areas. Continue treatment twice a day for 4 weeks. To prevent jock itch, keep the groin and anal areas clean and dry, avoid chaffing and launder athletic supports frequently. For treatment, use Miconazole Nitrate 2% Solution in the same manner over the affected area. Continue treatment for 2 weeks.

Fingernails and Toenails-General Information: Your nails are produced from cells in the tips of your fingers and toes and are composed of laminated layers a protein called "Keratin". Each nail grows towards the end of your finger or toe from a nail root that extends back into a groove of skin. Just in front of your nail root is your cuticle skin, which is attached to the nail surface and helps protect the new keratin cells that slowly emerge from below. The following lists conditions that may develop in your nails and how to take proper care of your nails.

Paronychia Signs and Symptoms: (Red swollen area on the skin next to a nail): Paronychia is a superficial infection of the skin around the nail, most commonly caused by either staphylococci or yeast. Superficial pus blisters may appear. Pressing the affected area can produce oozing pus. Paronychia may also be caused by fungal infections and is common among those with diabetes mellitus and those who may have their hands in water for long periods. Like other fungal infections, paronychia may develop slowly, but prove to be very persistent. To treat the infection, soak the affected area in clean, warm water. This will help decrease inflammation of the tissues. After soaking, apply an antibacterial or antifungal agent to the affected area. Consult a doctor if you are not sure whether a paronychia infection is bacterial or fungal.

Fungal Infections of the Nails: Fungus spores may attach themselves to the dense bed of keratin cells that make up your nails. These microscopic organisms can then digest the keratin and live within it. The resulting infection is called Onychomycosis (tinea of the nails), may persist indefinitely. It can cause nails to thicken, discolor, become lusterless and crumble along the edges. Onychomycosis can be contracted by walking barefoot in public places or may develop as a complication of athlete's foot. The associated infection of the foot or hand may be mild, producing no inflammation, or it may be acute, accompanied by blisters and painful swelling. Once the nails become involved, they may even become detached and shed and may be entirely destroyed. Consult a doctor if you suspect an Onychomycosis infection. A simple test can identify the fungus and rule out other diseases of the nails. A topical antifungal solution, such as Miconazole Nitrate 2% Solution can treat the skin under the nails and surrounding cuticle area but will not penetrate the nails themselves. If you have a fungal infection that is disabling or excessively disfiguring, consult your doctor to find out the best treatment for you.

GENERAL INFORMATION About Miconazole Nitrate 2% Solution:

Important Tips on Using Miconazole Nitrate 2% Solution:

Use Miconazole Nitrate 2% Solution as soon as an infection is detected. This will kill the fungus before it gets out of control and prevents it from spreading to other areas.

HOW SUPPLIED

NDC# 50268-503-29

1 fl. oz. (29.57mL) bottle with brush applicator containing an alcohol-free clear solution.

For more information, see enclosed package insert.

Questions?

FREQUENTLY ASKED QUESTIONS:

What is the active ingredient in Miconazole Nitrate 2% Solution?

Miconazole Nitrate 2% Solution contains 2% miconazole nitrate, the maximum strength antifungal allowed by the FDA without a prescription.

Do I apply Miconazole Nitrate 2% Solution to the nail?

No, nothing penetrates nails. Fungus is not growing on the nail but on the nail bed (skin). Apply Miconazole Nitrate 2% Solution on skin under nails and surrounding cuticle areas twice a day (morning and evening).

When can I expect results?

You may start seeing results in as little as 4 to 6 weeks.

How long does it take for a nail to grow?

It could take 8 to 10 months for a nail to grow out completely.

Why does your package say: "This product is not effective on the scalp or nails"?

In 1994, the FDA ruled that no over-the-counter antifungal product is effective on the nails. The FDA's opinion was that antifungal products available without a prescription could not penetrate the nails and are therefore, ineffective in treating them. The statement "this product is not effective on scalp or nails" was subsequently required on the labels of all over-the-counter antifungal products. Fungus is an infection of the skin, not the nail.

Can I use Miconazole Nitrate 2% Solution for Athlete's Foot?

Yes, Miconazole Nitrate 2% Solution is a potent antifungal. It treats athlete's foot and ringworm. For athlete's foot and ringworm, apply Miconazole Nitrate 2% Solution to the affected area twice a day for 4 weeks; pay special attention to spaces between the toes.

Can children use Miconazole Nitrate 2% Solution?

Miconazole Nitrate 2% Solution is safe and effective for children over 2 years of age. Children under 2 years of age, use only under physician supervision.

What happens if Miconazole Nitrate 2% Solution spills?

Care should be taken to avoid spilling because Miconazole Nitrate 2% Solution may damage counter tops, porcelain, stainless steel, flooring, etc.

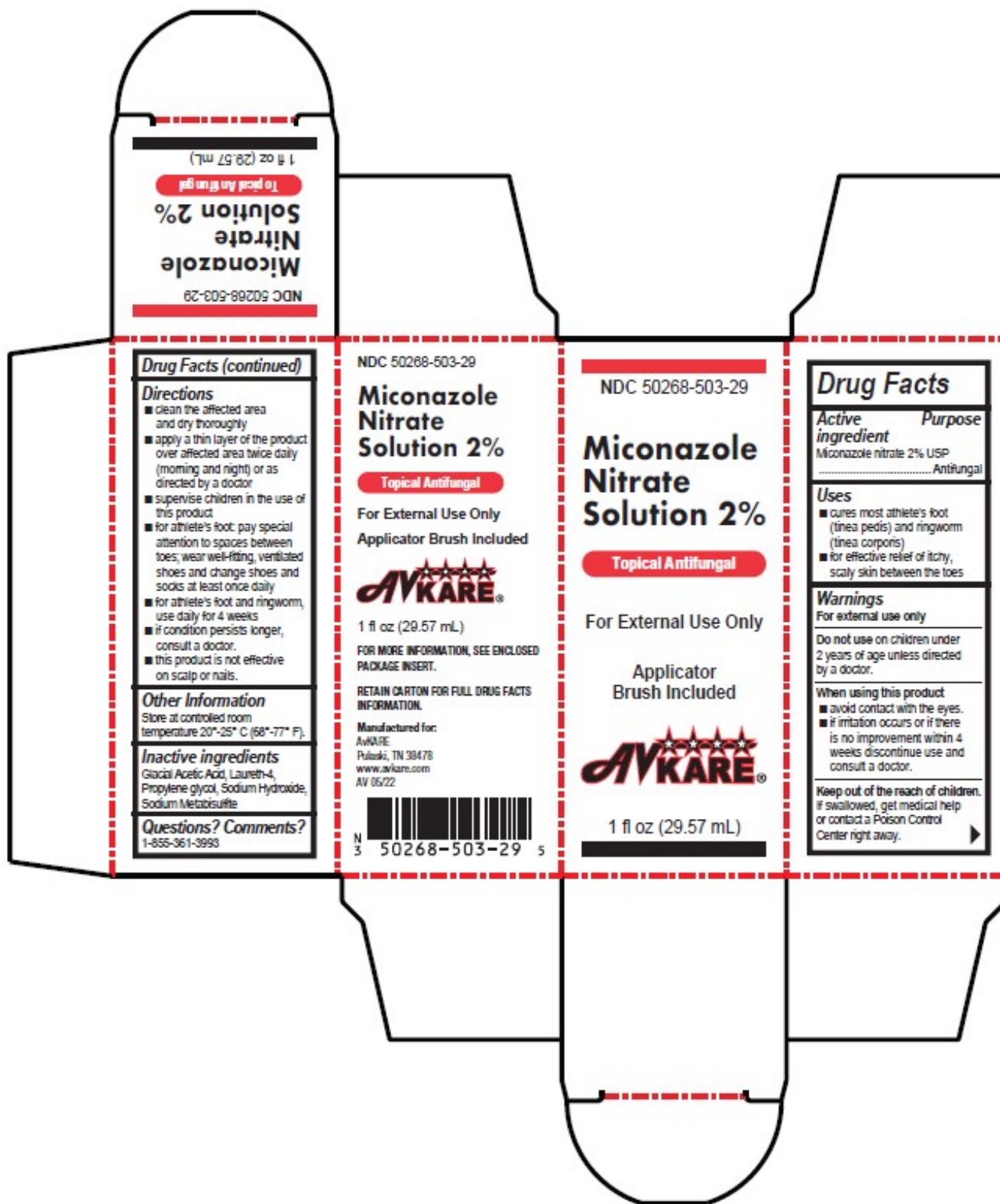
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AvKARE, Pulaski, TN 38478

www.avkare.com

AV 07/2022

PRINCIPAL DISPLAY PANEL - 29.57 mL Bottle Carton



MICONAZOLE NITRATE

miconazole nitrate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50268-503
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ACETIC ACID (UNII: Q40Q9N063P)	
LAURETH-4 (UNII: 6HQ855798J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-503-29	29.57 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	10/13/2022	

Labeler - AvPAK (832926666)

Revised: 12/2022

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