GREEN TETTERINE- miconazole nitrate ointment S.S.S. Company

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.

DRUG FACTS

Active Ingredient:

Miconazole Nitrate 2%

Purpose:

Antifungal

Uses

treats most athlete's foot, jock itch and ringworm. Relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort, and chafing associated with jock itch. Relieves itchy, scaly skin between the toes or itching, burning feet associated with athlete's foot.

Ask your health professional regarding additional uses

Warnings

Do not use on children under 2 years of age unless directed by a doctor

For external use only

When using this product

Avoid contact with the eyes

Stop using and ask a doctor if

- for athlete's foot and ringworm, irritation occurs or if there is no improvement within 4 weeks.
- for jock itch if irritation occurs or if there is no improvement with-in 2 weeks

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Clean the affected area and dry thoroughly. Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete's foot pay special attention to spaces between the toes, wear well fitting ventilated shoes, and change shoes and socks at least once daily. For athlete's foot and ringworm use daily for 4 weeks. For jock itch, use daily for 2 weeks. If condition persists longer consult a doctor. This product is not effective on the scalp or nails.

Other Information

store at 15°-30°C (59°-86°F)

To report a serious adverse event or for product information contact (404) 521-0857.

Other Ingredients

FD&C blue #1, fragrance, paraffin wax, petrolatum, and starch

Principal Display Panel

NDC 12258-241-01

Tetterine®

Ointment

Antifungal

Cures: Athlete's Foot,

Jock Itch and Ringworm

Net wt. 1oz. (28.4g.)

Other Packaging Content

Manufactured by S.S.S. Company Atlanta, GA 1-800-237-3843

www.ssspharmaceuticals.com

Rev. B

RETAIN THIS CARTON FOR FUTURE REFERENCE!



www.ssspharmaceuticals.com

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Net wt. 1 oz. [28.4 g.]

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Manufactured by S.S.S. Company, Atlanta, GA 30315 www.ssspharmaceuticals.com

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GREEN TETTERINE

miconazole nitrate ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12258-241
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO 0 D7S5M)	MICONAZOLE NITRATE	2 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)		
PETROLATUM (UNII: 4T6H12BN9U)		
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ0 O 6 29 4)		

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:12258-241-01	1 in 1 CARTON	07/31/1994	
	1	28.4 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	07/31/1994	

Labeler - s.s.s. Company (003288321)

Establishment				
Name	Address	ID/FEI	Business Operations	
S.S.S. Company		003288321	manufacture(12258-241), pack(12258-241), label(12258-241)	

Revised: 11/2020 S.S.S. Company