TRIPLE ANTIFUNGAL- miconazole nitrate ointment
Advantice Health, LLC

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.

Triple Paste Antifungal Ointment

Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- For the treatment of superficial skin infections caused by yeast *(Candida albicans)*
- Relieves discomfort, irrit.ation, redness and chafing associated with jock itch
- Cures most jock itch (tinea cruris)

Warnings

For external use only

When using this product avoid contact with the eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within 2 weeks

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

Keep out of reach of children.

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

Directions

- Clean affected area and dry thoroughly
- Apply a thin layer of product over affected area twice daily (morning and night) or as directed by a doctor
- Supervise children in the use of this product
- 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 room temperature 15°– 30°C (59°– 86°F)

Inactive ingredients

White petrolatum, zinc oxide, corn starch, anhydrous lanolin, stearyl alcohol, beeswax, cholesterol.

Questions?

1-800-345-0032

Distributed by Advantice Health, LLC
Cedar Knolls, NJ 07927

PRINCIPAL DISPLAY PANEL - 56.7 g Tube Carton

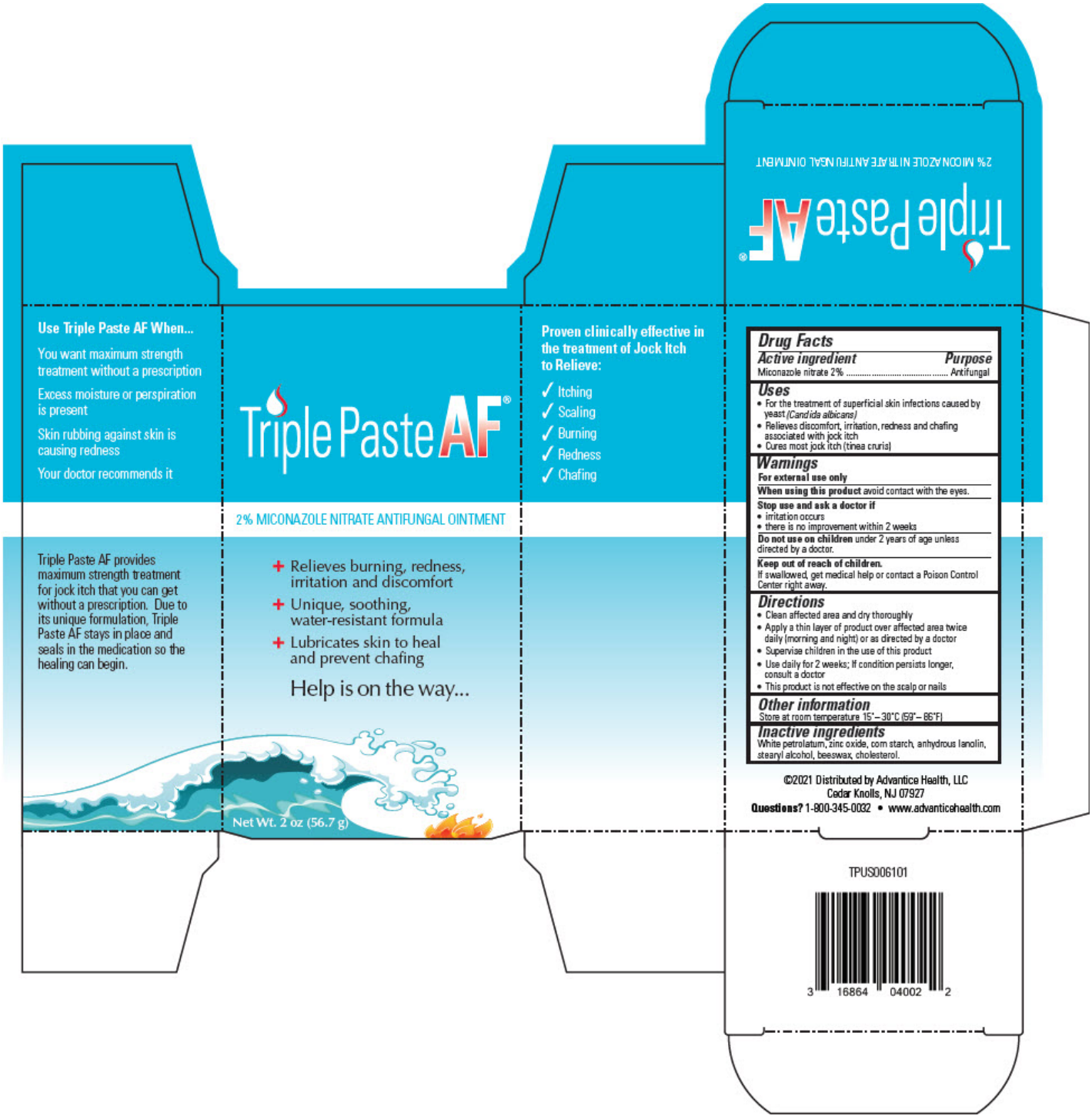
Triple Paste AF®

2% MICONAZOLE NITRATE ANTIFUNGAL OINTMENT

- Relieves burning, redness, irritation and discomfort
- Unique, soothing, water-resistant formula
- Lubricates skin to heal and prevent chafing

Help is on the way...

Net Wt. 2 oz (56.7 g)



TRIPLE ANTIFUNGAL

miconazole nitrate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16864-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	Miconazole Nitrate	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
STARCH, CORN (UNII: O8232NY3SJ)	
LANOLIN (UNII: 7EV65EAW6H)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LEVOMENOL (UNII: 24WE03BX2T)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
OAT (UNII: Z6J799EAJK)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16864-040-02	1 in 1 CARTON	09/01/2021	
1		56.7 g in 1 TUBE; 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	09/01/2021	

Labeler - Advantice Health, LLC (192527062)

Revised: 9/2021 Advantice Health, LLC