TRIPLE AF- miconazole nitrate paste
Summers Laboratories Inc

SUMMERS LABS (as PLD) - TRIPLE PASTE AF (11086-040)

ACTIVE INGREDIENT

MICONAZOLE NITRATE 2%

PURPOSE

ANTIFUNGAL

Uses

- For the treatment of superficial skin infections caused by yeast (Candida albicans).
- Relieves discomfort, irritation, 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 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 CONTCT 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

Inactive ingredients

White petrolatum, zinc oxide, corn starch, anhydrous lanolin, stearyl alcohol, beeswax, cholesterol, polysorbate 80.

TRIPLE AF

miconazole nitrate paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11086-040
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
PETROLATUM (UNII: 4T6H12BN9U)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
STARCH, CORN (UNII: O8232NY3SJ)	
LANOLIN (UNII: 7EV65EAW6H)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11086-040-01	28.7 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2013	
2	NDC:11086-040-02	57 g in 1 TUBE; Type 0: Not a Combination Product	10/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	10/30/2013	

Labeler - Summers Laboratories Inc (002382612)

Revised: 10/2023 Summers Laboratories Inc