

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 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

Inactive ingredients

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

<p>Use Triple Paste AF When...</p> <p>Typical creams, powders and sprays have failed</p> <p>Excess moisture or perspiration is present</p> <p>Skin rubbing against skin is causing redness</p> <p>Your doctor recommends it</p>	<p>Labeled for Healthcare Professional Use</p> <p>Triple Paste AF[®]</p>	<p>Leading physicians recommend Triple Paste AF</p> <p>Unconditional Satisfaction Guarantee If Triple Paste AF is not the best antifungal you have ever used, we will refund your full purchase price. Visit TriplePasteAF.com/guarantee for details.</p>	<table border="1"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Miconazole nitrate 2%</td> <td>Antifungal</td> </tr> <tr> <td colspan="2">Uses</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> For the treatment of superficial skin infections caused by yeast (<i>Candida albicans</i>) Relieves discomfort, irritation, redness and chafing associated with jock itch Cures most jock itch (tinea cruris) </td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">When using this product: Avoid contact with the eyes.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> irritation occurs there is no improvement within 2 weeks </td> </tr> <tr> <td colspan="2">Do not use on children under 2 years of age unless directed by a doctor.</td> </tr> <tr> <td colspan="2">Keep out of reach of children.</td> </tr> <tr> <td colspan="2">If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> 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 </td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">White petrolatum, zinc oxide, corn starch, anhydrous lanolin, stearyl alcohol, beeswax, cholesterol, polysorbate 80.</td> </tr> <tr> <td colspan="2">Distributed by: Summers Laboratories, Inc. Collingville, PA 19426 1-800-533-SKIN (7548) • www.TriplePasteAF.com</td> </tr> </table>	Drug Facts		Active ingredient	Purpose	Miconazole nitrate 2%	Antifungal	Uses		<ul style="list-style-type: none"> For the treatment of superficial skin infections caused by yeast (<i>Candida albicans</i>) 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 the eyes.		Stop use and ask a doctor if		<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> 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.		Distributed by: Summers Laboratories, Inc. Collingville, PA 19426 1-800-533-SKIN (7548) • www.TriplePasteAF.com	
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<p>Triple Paste AF provides the most effective treatment for jock itch that you can get without a prescription. Due to its unique formulation, Triple Paste AF stays in place and seals in the medication so the healing can begin.</p> <p>When other antifungal treatments have failed, doctors recommend Triple Paste AF.</p>	<p>2% MICONAZOLE NITRATE ANTIFUNGAL OINTMENT</p> <ul style="list-style-type: none"> + Relieves burning, redness, irritation and discomfort + Unique, soothing, water-resistant formula + Lubricates skin to heal and prevent chafing <p>Help is on the way... Guaranteed</p> <p>For more information visit us at www.TriplePasteAF.com</p> <p>Net Wt (56.7 g) 2 oz</p>																																						

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: VV4H1CYW1K) (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: O8232NY3S)	
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