

**CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULA-
tolnaftate solution**
Triple Point Group, 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.

CRYSTAL FLUSH Maximum Strength Anti-Fungal Formula

Active Ingredient

Tolnaftate 1%

Purpose:

Anti-fungal

Uses:

Effective treatment for athlete's foot (tinea pedis) and ringworm (tinea corporis). For the effective relief of itching, scaling, cracking and discomforts which may accompany these conditions.

Warnings:

For external use only.

- Avoid contact with the eyes.
- Do not use on children under 2 years of age unless directed by a doctor.
- If treating athlete's foot and ringworms: Stop use and consult a doctor if irritation occurs or if there is no improvement within 4 weeks.
- If swallowed, get medical help or contact a Poison Control Center right away.

Keep this and all drugs out of the reach of children.

Directions:

Clean or wash 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 doctor. For athlete's foot, pay special attention to space between 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. Supervise children in the use of this product.

Inactive ingredients:

Prunus Amygdalus Dulcis (Sweet Almond) Oil, Cymbopogon Nardus (Citronella) Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Simmondsia Chinensis (Jojoba) Oil, Syzygium Aromaticum (Clovebud) Oil, Azadirachta Indica (Neem) oil, Tocopheryl Acetate (Vitamin E).

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**CRYSTAL
FLUSH™**

**MAXIMUM STRENGTH
ANTI-FUNGAL FORMULA**

.5FL OZ (15ML)

DRUG FACTS:
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Distributed By:
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CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULA

tolnaftate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80569-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
JOJOBA OIL (UNII: 724GKU717M)	
CLOVE OIL (UNII: 578389D6D0)	
AZADIRACHTA INDICA SEED OIL (UNII: 4DKJ9B3K2T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80569-101-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/07/2021	

Labeler - Triple Point Group, LLC (058482713)**Registrant** - Triple Point Group, LLC (058482713)

Revised: 4/2021

Triple Point Group, LLC