CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULAtoInaftate 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.

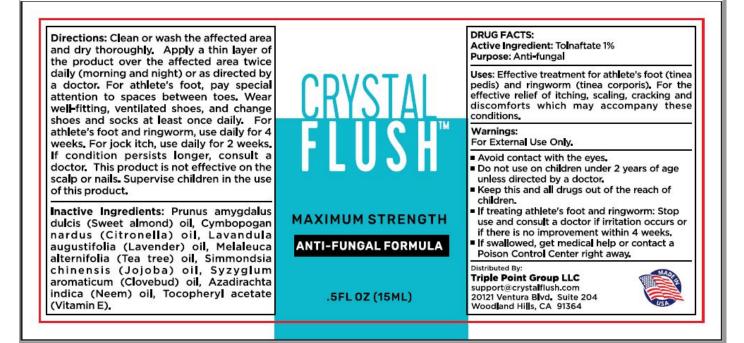
Keep this and all drugs out of the reach of children.

Directions:

Clean or wash the affected area and dry throughly. Apply a thin layer of the product over the affected area twice daily (morning and night) or as directed by doctor. For athletes 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, Cymbopogan 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).



CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULA

tolnaftate solution

HUMAN OTC DRUG	Item Code	(Source)	NDC:	80569-101
TOPICAL				
Moiety				
ient Name		Basis of Stren	gth	Strength
TOLNAFTATE - UNII:06KB62	9TKV)	TOLNAFTATE		1 g in 100 mL
Ingredient Name				Strength
′D0)				
3)				
(UNII: 4DKJ9B3K2T)				
(UNII: 9E8X80D2L0)				
	TOPICAL Moiety ient Name (TOLNAFTATE - UNII:06KB62	TOPICAL Moiety ient Name (TOLNAFTATE - UNII:06KB629TKV) Ingredient Name (D0) 3) (UNII: 4DKJ9B3K2T)	TOPICAL Moiety ient Name (TOLNAFTATE - UNII:06KB629TKV) TOLNAFTATE Ingredient Name (D0) (UNII: 4DKJ9B3K2T)	TOPICAL Moiety ient Name Basis of Strength TOLNAFTATE - UNII:06KB629TKV) TOLNAFTATE Ingredient Name DO (UNII: 4DKJ9B3K2T)

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2021	
Marketing I	nformation		
Marketing I Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - Triple Point Group, LLC (058482713)

Registrant - Triple Point Group, LLC (058482713)

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Triple Point Group, LLC