

**CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULA- undecylenic acid 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**

Undecylenic Acid 25%

**Purpose**

Anti-fungal

**Uses:**

For cure of most:

- ringworm (tinea corporis)
- athlete's foot (tinea pedis).

For the relief of:

- itching
- scaling
- cracking
- burning
- redness
- soreness
- irritation and discomforts which may accompany these conditions.

**Warnings:**

For external use only.

- Ask a doctor before use on children under two years of age. DO NOT USE on diaper rash.

When using this product avoid contact with eyes.

Stop use and ask a doctor if

- irritation occurs
- there is no improvement within four weeks.

If pregnant or breast-feeding, ask a health professional before use.

**KEEP OUT OF REACH OF CHILDREN.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions:**

- Clean and dry affected area with soap and water and dry thoroughly.
- Apply a thin layer to the affected area twice daily (morning and night) or as directed by physician.
- For athlete's foot, pay special attention to the space between the toes, and wear well-fitting ventilated shoes and socks. For athlete's foot and ringworm. If Conditions persists for longer, consult a physician.
- Intended for use typically by healthy adults only. Persons under the age of 18, or those with highly sensitive or allergic skin should use only as directed by physician.
- This product is not meant to be applied directly to the Scalp or nails.

**Other ingredients:**

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

<p>Directions: ■ Clean and dry affected area with soap and water and dry thoroughly. ■ Apply a thin layer to the affected area twice daily (morning and night) or as directed by physician. ■ For athlete's foot, pay special attention to the space between the toes, and wear well-fitting ventilated shoes and socks. For athlete's foot and ringworm. If conditions persists for longer, consult a physician. ■ Intended for use typically by healthy adults only. Persons under the age of 18, or those with highly sensitive or allergic skin should use only as directed by physician. ■ This product is not meant to be applied directly to the scalp or nails.</p> <p>Other ingredients: Cymbopogan Nardus (Citronella) Oil, Lavandula Angustifolia (Lavender) Oil, Melaleuca Alternifolia (Tea Tree) Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Simmondsia Chinensis (Jojoba) Oil, Syzygium Aromaticum (Clovebud) Oil, Tocopheryl Acetate (Vitamin E).</p>		<p><b>DRUG FACTS:</b></p> <table border="1"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Undecylenic Acid 25%</td> <td>Anti-fungal</td> </tr> </table> <p>Uses: For cure of most: ■ ringworm (tinea corporis) ■ athlete's foot (tinea pedis). For the relief of: ■ itching ■ scaling ■ cracking ■ burning ■ redness ■ soreness ■ irritation and discomforts which may accompany these conditions.</p> <p>Warnings: For external use only.</p> <p>■ Ask a doctor before use on children under two years of age. DO NOT USE on diaper rash. When using this product avoid contact with eyes. Stop use and ask a doctor if ■ irritation occurs ■ there is no improvement within four weeks. KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.</p> <p>Distributed By: Triple Point Group LLC support@crystalflush.com 20121 Ventura Blvd, Suite 204, Woodland Hills, California 91364</p>	Active Ingredient	Purpose	Undecylenic Acid 25%	Anti-fungal
Active Ingredient	Purpose					
Undecylenic Acid 25%	Anti-fungal					

CRYSTAL FLUSH MAXIMUM STRENGTH ANTI-FUNGAL FORMULA			
undecylenic acid solution			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80569-184
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>UNDECYLENIC ACID</b> (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	25 g in 100 mL	

## Inactive Ingredients

Ingredient Name	Strength
CITRONELLA OIL (UNII: QY08Q067D0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TEA TREE OIL (UNII: VIF565UC2G)	
ALMOND OIL (UNII: 66YXD4DKO9)	
JOJOBA OIL (UNII: 724GKU717M)	
CLOVE OIL (UNII: 578389D6D0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80569-184-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/17/2020	

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

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

Revised: 3/2021

Triple Point Group, LLC