

DEFENSE ANTIFUNGAL MEDICATED BAR- tolnaftate soap

Defense Soap 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.

Defense Antifungal Medicated Bar

Active ingredient

Tolnaftate 1%

Purpose

Antifungal

Uses

- Proven clinically effective in the treatment of most athlete's foot (tinea pedis) & ringworm (tinea corporis).
- For effective relief of itching, burning & cracking.

Warnings

For external use only

When using this product

When using this product avoid contact with the eye

Stop use and ask a doctor if

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- irritation occurs
- there is no improvement within 4 weeks

Do not use

Do Not use on children under 2 under of age except under the advice and supervision of a doctor.

Keep out of reach of children.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wash affected area well and let product sit 1-2 minutes before rinsing.
- Make sure to dry affected area thoroughly. Supervise children in the use of this product.
- For Athlete's foot: pay special attention to the spaces between the toes; wear well-fitting, ventilated shoes and change shoes and socks at least once daily.
- Use 1-2 times daily. Use daily for 4 weeks; if condition persists longer, ask a doctor.
- This product is not effective on the scalp or nails.

Other information

Store between 20 to 25C (68 to 77F)

Inactive ingredients

Sodium Palmate, Sodium Palm Kernelate, Water, Glycerin, Sodium Gluconate, Eucalyptus Globulus Leaf Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Palm Acid, Sodium Chloride, Palm Kernel Acid

Questions or comments?

1-866-544-1689

www.DefenseSoap.com

Principal Display Panel

Tolnaftate 1%

Antifungal

Medicated Bar Soap

Cures and Prevents Most Fungal Skin Infections, Including Athlete's Foot, Ringworm and Tinea Versicolor.



DEFENSE ANTIFUNGAL MEDICATED BAR

tolnaftate soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70856-3434
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 g

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)	
WATER (UNII: 059QF0KO0R)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
GLYCERIN (UNII: PDC6A3C0OX)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
PALM ACID (UNII: B6G0Y5Z616)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PALM KERNEL ACID (UNII: 79P21R4317)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70856-3434-3	1 in 1 CARTON	08/01/2016	
1		119 g in 1 NOT APPLICABLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	08/01/2016	

