PURIYA ANTIFUNGAL BALM- zinc undecylenate cream Raining Rose, Inc.

Puriya Antifungal Balm

DRUG FACTS

Active Ingredient

Zinc Undecylenate 10%

Purpose

Antifungal

Uses • Treats athlete's loot, jock itch and ringworm • Relieves itchlng, burning, cracking and scaling which accompany these conditions

Warnings

For external use only

Do oot use In children under 2 years of age unless directed by doctor

When using this product • Do not get into eyes

Stop use and ask doctor if • Irritation occurs • there is no improvement within 4 weeks (for athlete's foot or ringworm) or 2 weeks (for jock Itch)

Keep out of reach of children • If swallowed, get medical help or call a Poison Control Center immediately.

Directions • Test asmall area on your skin to check for any potential allergic reaction • Wash affected area and dry thoroughly • Apply a thin layer over affected area twice dally (morning and night) or as directed by a doctor • Supervise children in use of this product • For athlete's foot, pay special attention to spaces between the toes, wear well-fitting, ventilated shoes and change socks at least once dally • For athlete's foot and ringworm, use dally for 4 weeks. For jock itch, use dally for 2 weeks • If condition persists longer, ask a doctor • This product is not effective on scalp or nails.

Other infonnation

Store between 68°F - 78°F (20°C - 25°C)

Inactive Ingredients:

Macadamia Temifolia (Macadamia) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Euphorbia Cerifera (Candelilla) Wax, Melaleuca Altemifolia (Tea Tree) Leaf Oil, Persea Gratissima (Avocado) Oil, Cocos Nucifera (Coconut) Oil, Eucalyptus Globulus Leaf Oil, Cetearyl Alcohol*, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Pelargonium Graveolens (Geranium) Flower Oil, Oryza Sativa (Rice) Bran Extract, Helianthus Annuus (Sunflower) Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, Cucurbita Pepo (Pumpkin) Seed Oil, Bisabolol, Lavandula Angustifolia (Lavender) Flower Oil, Citrus Aurantium Dulcis (Orange) Peel Oil. *Derived from plant sources

Questions? Comments? 844-234-1476

Product Labeling puriya®

ANTIFUNGAL BALM

Treats Athlete's Foot | Jock Itch | Ringworm Physician Formulated |16 Powerful Botanicals

Zinc Undecylenate

Net wt 2.0 oz / 57 g

Distributed by: IPC Republic, Inc. DBA Puriya Los Angeles, CA 90013 844-234-1476

www.puriya.com

Questions? Email usatservice@Puriya.com

Box



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PURIYA ANTIFUNGAL BALM

zinc undecylenate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65692-0308

Route of Administration TOPICAL

Active Ingredient/Active Moiety Basis of Ingredient Name Strength **Strength** ZINC UNDECYLENATE (UNII: 388VZ 25DUR) (UNDECYLENIC ACID -5.7 g ZINC UNDECYLENATE UNII:K3D86KJ24N) in 57 g

Inactive Ingredients	
Ingredient Name	Strength
MACADAMIA OIL (UNII: 515610SU8C)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CANDELILLA WAX (UNII: WL0328HX19)	
TEA TREE OIL (UNII: VIF565UC2G)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
COCONUT OIL (UNII: Q9L0O73W7L)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ALMOND OIL (UNII: 66YXD4DKO9)	
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
RICE BRAN (UNII: R60QEP13IC)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PUMPKIN SEED OIL (UNII: 6E5QR5USSP)	
LEVOMENOL (UNII: 24WE03BX2T)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

ORANGE		

Packaging								
# Item Code	Package Description	Marketing Start Date	Marketing End Date					
NDC:65692- 0308-1	1 in 1 BOX	06/04/2021						
1	5.7 g in 1 JAR; Type 0: Not a Combination Product							

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC Monograph Drug	M005	06/04/2021				

Labeler - Raining Rose, Inc. (083819404)

Revised: 11/2023 Raining Rose, Inc.