ROYCEDERM TEA TREE BODY WASH- tea tree body wash gel RoyceDerm LLC

Initial Drug Listing - RoyceDerm Tea Tree Body Wash

Tolnaftate 1.0%

Anti-Fungal

- Helps relieve and prevent athlete's foot(tinea pedis), jock itch (tinea cruris),ringworm(tinea corporis)
- Relieves itching, cracking, scaling, and discomfort caused by these fungal infections

For external use only

on children under 12 of age except under the advice and supervision of a doctor.

Ask a doctor before use if allergic to anying redients in this product.

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop and ask a doctor if irritation occurs or if there is no improvement within 2 weeks for jock itch or within 4 weeks for athlete's foot and ringworm.

ask a health professional before use

In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away.(1-800-222-1222)

- Apply to body and feet during shower or bath.
- Gently massage over the entire body, focusing on areas where odor or skin irritation is a concern.
- After gently washing, rinseand dry skin and feet thoroughly.
- For Athllete'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. This product is not effective on the scalp or nails.

Store at 20° to 25°C(68° to 77°F) and out of direct sunlight.

Purified Water, Artemisia Argyi Leaf, TeaTree Oil, Shea Butter, Sophora Flavescens Root Extract, Cnidium Monnieri Fruit, Lentinula Edodes (Shiitake Mushroom) Extract, Gleditsia Sinensis Fruit, Typhonium Giganteum Whole, Stemona Tuberosa Root, Citric Acid, Amino Acids

Email service@roycederm.com





TEATREE BODY WASH

Anti-bacterial & Anti-fungal



Soothes Dry, Itchy Skin, Reduce Skin Irritation, Acne & Body Odor

> Extra-Strength Exfoliation **Deeply Moisturizes** Gentle on Sensitive Skin

16.9 FL. OZ. / 500 ML $\,\mathrm{e}$

Drug Facts

Active ingredient Tolnaftate 1.0%.

Purpose

Anti-Fungal

■ Helps relieve and prevent athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis) ■ Relieves itching, cracking, scaling, and discomfort caused by these fungal infections

Warnings

For external use only

Do not use on children under 12 of age except under the advice and supervision of

Ask a doctor before use if allergic to any ingredients in this product.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop and ask a doctor if irritation occurs or if there is no improvement within 2 weeks for jock itch or within 4 weeks for athlete's foot and ringworm.

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

Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away. (1-800-222-1222)

Directions

 Apply to body and feet during shower or bath.

Gently massage over the entire body, focusing on areas where odor or skin irritation is a concern.

After gently washing, rinse and dry skin and feet thoroughly.

Drug Facts (Continued)

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. This product is not effective on the scalp or nails.

Other information

Store at 20° to 25°C (68° to 77°F) and out of direct sunlight.

Inactive ingredients

Purified Water, Artemisia Arqvi Leaf, Tea Tree Oil, Shea Butter, Sophora Flavescens Root Extract, Cnidium Monnieri Fruit, Lentinula Edodes (Shiitake Mushroom) Extract, Gleditsia Sinensis Fruit, Typhonium Giganteum Whole, Stemona Tuberosa Root, Citric Acid, Amino Acids

Questions or comments?

Email service@rovcederm.com

Distributed by

RoyceDerm LL Sheridan, WY 82801 Customer care: service@rovcederm.com







EXPERT TIPS

ROYCEDERM TEA TREE BODY WASH

tea tree body wash gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85424-002

TOPICAL Route of Administration

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLEDITSIA SINENSIS FRUIT (UNII: A6W0J6UO7Q)	
CITRIC ACID (UNII: 2968PHW8QP)	
AMINO ACIDS (UNII: 0072R8RF8A)	
LENTINULA EDODES MYCELIUM (UNII: CU2S39TB8O)	
WATER (UNII: 059QF0KO0R)	
CNIDIUM MONNIERI FRUIT (UNII: V1IA3S3CUS)	
ARTEMISIA ARGYI LEAF (UNII: 2JYC99Q0WZ)	

SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
SAUROMATUM GIGANTEUM WHOLE (UNII: C61Y66MY4H)	
SHEA BUTTER (UNII: K49155WL9Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
STEMONA TUBEROSA ROOT (UNII: 7S9328671Z)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:85424-002- 01	500 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	08/01/2025	

Labeler - RoyceDerm LLC (130329531)

Registrant - RoyceDerm LLC (130329531)

Revised: 11/2025 RoyceDerm LLC