ROYCEDERM COOLDEFENSE REFRESHING SHOWER GEL- tolnaftate 1.0% liquid RoyceDerm LLC

Initial Drug Listing - RoyceDerm CoolDefense & Refreshing SHOWER GEL

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 years of age.

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

Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.

If pregnancy 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.

- Apply a generous amount to wet skin.
- Massage gently to create a rich lather.
- Leave on for 1-2 minutes for maximum benefits.
- Rinse thoroughly with water.
- Use daily for best results.
- 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.

Store in a cool, dry place. Keep away from direct sunlight and heat sources.

Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Eucalyptus Globulus Leaf Oil, Menthol, Aloe Barbadensis Leaf Juice, Avena Sativa (Oat) Kernel Extract, Olea Europaea (Olive) Fruit Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopheryl Acetate (Vitamin E), Citric Acid, Sodium Chloride, Phenoxyethanol, Ethylhexylglycerin

Email service@roycederm.com



ROYCEDERM COOLDEFENSE REFRESHING SHOWER GEL

tolnaftate 1.0% liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85424-007
Route of Administration	TOPICAL		

Strength
1 g in 100 mL
1

Inactive Ingredients	
Ingredient Name	Strength
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)	
AQUA (UNII: 059QF0KO0R)	

EUCALYPTUS GLOBULUS LEAF OIL (UNII: 2R04ONI662)	
AVENA SATIVA (OAT) KERNEL OIL (UNII: 3UVP41R77R)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MENTHOL (UNII: L7T10EIP3A)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424- 007-01	2 in 1 CARTON	08/31/2025	
1		250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M005	08/31/2025		

Labeler - RoyceDerm LLC (130329531)

Revised: 7/2025 RoyceDerm LLC