

ROYCEDERM TEA TREE THERAPEUTIC- salicylic acid 3% gel

RoyceDerm LLC

Initial Drug Listing - RoyceDerm Tea Tree Therapeutic Shampoo

Salicylic Acid 3%

Anti-dandruff, anti-psoriasis, anti-seborrheic dermatitis

- Helps control dandruff
- Relieves itching, scaling, and flaking associated with dandruff

For external use only

- Do not use it on damaged or inflamed scalp.
- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- If condition worsens or does not improve after regular use.
- If children under 12 years old, and pregnant or breast-feeding.
- If swallowed, get medical help or contact a poison control center.

Keep out of reach of Children.

Apply shampoo, massage into the scalp, and leave on hair for 3-5 minutes to allow maximum absorption. Then rinse thoroughly and repeat as needed. For best results, use at least twice a week or as directed by a doctor.

Aqua, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Potassium Cocoyl Glycinate, Cocamidopropyl Betaine, Cocamide MEA, Cocamide Methyl MEA, Sodium Chloride, Glycol Distearate, Acrylates Copolymer, Cetearyl Alcohol, Hydroxyacetophenone, 1,2-Hexanediol, Glycerin, Dipropylene Glycol, Bisamino PEG/PPG-41/3 Aminoethyl PG-Propyl Dimethicone, Guar Hydroxypropyltrimonium Chloride, Piroctone Olamine, Polyquaternium-10, PEG-12 Dimethicone, Citric Acid, Polyquaternium-7, Menthol, Menthyl Lactate, Mentha Haplocalyx Oil, Disodium EDTA, Sodium Hydroxide, Butylene Glycol, Trehalose, PEG-150 Distearate, Gardenia Jasminoides Fruit Extract, Zingiber Officinale (Ginger) Root Extract, Triticum Vulgare (Wheat) Germ Oil, Aloe Barbadensis Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Centella Asiatica Extract, Scutellaria Baicalensis Root Extract, Polygonum Cuspidatum Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract.

Visit www.roycederm.com
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85424-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)			SALICYLIC ACID	3 mg in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
CITRIC ACID (UNII: 2968PHW8QP)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)				
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)				
PANTHENOL (UNII: WW9CM0O67Z)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
GLYCERIN (UNII: PDC6A3C0OX)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-012-01	350 mL in 1 CARTON; Type 0: Not a Combination Product	12/15/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M032	12/15/2025	

Labeler - RoyceDerm LLC (130329531)