

ROYCEDERM TINEA ANTIFUNGAL .CREAM. AND .SOAP.- cream and soap
RoyceDerm LLC

Initial Drug Listing - RoyceDerm tinea ANTIFUNGAL CREAM and SOAP-176

Miconazole Nitrate 2%

Clotrimazole 1%

Antifungal

- For effective treatment of most athlete's foot (tinea pedis), ringworm(tinea corporis) and jock itch (tinea cruris).
- For effective relief of itching, burning, cracking and discomfort associated with these conditions.
- **For external use only**
- **When using this product**, avoid contact with the eye.
- **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.
- **Do not use on** children under 2 of age except under the advice and supervision of a doctor.

If swallowed, get medical help or contact a Poison Control Center right away.

- Wash the affected area and dry thoroughly.
- Apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor.
- 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.
- For athlete's foot and ringworm, use daily for 4 weeks;
- For jock itch, use daily for 2 weeks.
- If condition persists longer, ask a doctor.
- This product is not effective on the scalp or nails.

Store at room temperature and out of direct sunlight.

Cream:

Water, Artemisia Extract, Sophora Flavescens Root Extract, Cnidium Monnieri Fruit Extract, Kochia Scoparia Fruit Extract, Dictamnus Dasycarpus Root Extract, Smilax Glabra Root Extract

Soap:

Sorbitol, Sucrose, Stearic Acid, Propanediol, Sodium Lauroamphoacetate, Water, Lauric Acid, Glycerin, Sodium Hydroxide, Butyrospermum Parkii (Shea) Butter, Aloe Barbadensis Leaf Extract, Potassium Cocoyl Glycinate, Olea Europaea (Olive) Fruit Oil, Sulfur, Fragrance

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ROYCEDERM TINEA ANTIFUNGAL .CREAM. AND .SOAP.

cream and soap kit

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:85424-023

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-023-01	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	05/04/2026	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 CARTON	2 g in 226
Part 2	0 TUBE	1 g in 57

Part 1 of 2

ROYCEDERM TINEA ANTIFUNGAL .SOAP.

clotrimazole 1% soap

Product Information

Item Code (Source) NDC:85424-022

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	2.26 g in 226 g

Inactive Ingredients

Ingredient Name	Strength
BUTYROSPERMUM PARKII (SHEA) BUTTER (UNII: K49155WL9Y)	
FRAGRANCE LAVENDER ORC1800979 (UNII: 1B40MIN2W5)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
POTASSIUM COCOYL GLYCINATE (UNII: WZ70FUF22U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SULFUR (UNII: 70FD1KFU70)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)	
LAURIC ACID (UNII: 1160N9NU9U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-022-01	226 g in 1 CARTON; 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	05/04/2026	

Part 2 of 2**ROYCEDERM TINEA ANTIFUNGAL CREAM**

miconazole nitrate 2% cream

Product Information

Item Code (Source)	NDC:85424-011
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SMILAX GLABRA WHOLE (UNII: H51N91QNEB)	
BASSIA SCOPARIA POLLEN (UNII: 07A108ZKW5)	
DICTAMNUS DASYCARPUS ROOT (UNII: 6153LEN214)	
WATER (UNII: 059QF0KO0R)	
CNIDIUM MONNIERI FRUIT (UNII: V1A3S3CUS)	
WORMWOOD (UNII: F84709P2XV)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-011-01	57 g in 1 TUBE; 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	05/04/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M005	05/04/2026	

Labeler - RoyceDerm LLC (130329531)