

ROYCEDERM SULFUR SOAP.- sulfur soap

RoyceDerm LLC

Initial Drug Listing - RoyceDerm Sulfur Soap Bar

Sulfur 10.0%

Acne Treatment

For the treatment of acne.

Create a rich lather with the mesh bag, gently apply to affected areas, leaving it on the skin for 3 to 5 minutes. Rinse thoroughly with water and pat dry with a clean towel. Incorporate into your routine 1 to 3 times a day, or as directed by a doctor, for optimal results.

Store at room temperature and out of direct sunlight

Visit www.roycederm.com

- For external use only.
- Apply solely to acne-affected areas. Use caution when combining with other topical acne medications to prevent skin irritation and dryness.
- Avoid use on broken or large skin areas.
- Discontinue use and consult a doctor if excessive skin irritation occurs.
- When using this product avoid contact with eyes. If contact occurs, rinse the eyes thoroughly with water.

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

If swallowed, get medical help or contact a Poison Control center (1-800-222-1222) right away.

Water, Olea Europaea Fruit Oil, 0.25% Salicylic Acid, Lauric Acid, Stearic Acid, Sorbitol, Glycerin, Cocos Nucifera Oil, Elaeis Guineensis Oil, Botanical Acaricide, Potassium Cocate, Lanolin, Sophora japonica Extract, Aloe Extract, Sulfur Spring Extract, Ginseng, Coleus Forskohlii Root Oil, Tea Tree Essential Oil.

Uses for the treatment of acne

RoyceDerm Sulfur Soap is your ultimate solution for a variety of skin concerns. Formulated with precision by dermatologists, this soap is designed to combat acne, control oil, and address issues like enlarged pores. Its unique blend of natural volcanic sulfur, salicylic acid, and botanical extracts makes it a powerhouse for healthy and radiant skin.

PH BALANCED **CAUTION FREE** **SUITABLE FOR ALL SKIN TYPES**

Sulfur Soap
FAST ACNE RELIEF
pH-Balanced Formula

Infused with 10% Natural Volcanic Sulfur | Safely & Effectively Regulates Oil, Clears Acne & Purifies Pores | Enriched with Herbal Extracts for Smooth & Hydrated Skin

2 Bars 4 oz (116 g) Each / TOTAL NET WT. 8oz (232 g)

DRUG FACTS
ACTIVE INGREDIENT.....PURPOSE
Sulfur 10.0%.....Acne Treatment

USES For the treatment of acne.

DIRECTIONS
Create a rich lather with the mesh bag, gently apply to affected areas, leaving it on the skin for 3 to 5 minutes. Rinse thoroughly with water and pat dry with a clean towel. Incorporate into your routine 1 to 3 times a day, or as directed by a doctor, for optimal results.

OTHER INFORMATION
Store at room temperature and out of direct sunlight

QUESTIONS OR COMMENTS?
Visit www.roycederm.com

WARNINGS
■ For external use only. ■ Apply solely to acne-affected areas.
■ Use caution when combining with other topical acne medications to prevent skin irritation and dryness.
■ Avoid use on broken or large skin areas.
■ Discontinue use and consult a doctor if excessive skin irritation occurs.
■ When using this product avoid contact with eyes. If contact occurs, rinse the eyes thoroughly with water.
■ Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.
■ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

INACTIVE INGREDIENTS
Water, Olea Europaea Fruit Oil, 0.25% Salicylic Acid, Lauric Acid, Stearic Acid, Sorbitol, glycerin, Cocos Nucifera Oil, Elaeis Guineensis Oil, Botanical Acaricide, Potassium Cocate, Lanolin, Sophora japonica Extract, Aloe Extract, Sulfur Spring Extract, Ginseng, Coleus Forskohlii Root Oil, Tea Tree Essential Oil.

ROYCEDERM SULFUR SOAP.

sulfur soap

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85424-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	23.2 g in 232 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E)	
STYPHNOLOBIUM JAPONICUM FLOWER BUD (UNII: DES4RX1Z3E)	
ALOE (UNII: V5VD430YW9)	
SORBITOL (UNII: 506T60A25R)	
LAURIC ACID (UNII: 1160N9NU9U)	
ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z)	
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
COLEUS FORSKOHLII ROOT OIL (UNII: 5NXR7DJ9W0)	
POTASSIUM COCOATE (UNII: F8U72V8ZXP)	
LANOLIN (UNII: 7EV65EAW6H)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
TEA TREE OIL (UNII: VIF565UC2G)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85424-003-01	232 g in 1 CARTON; 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	M006	08/01/2025	

Labeler - RoyceDerm LLC (130329531)